NAT'L INST. OF STAND & TECH R.I.C.
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REFERENCE

NIST
PUBLICATIONS

NBS SPECIAL PUBLICATION 632

U.S. DEPARTMENT OF COMMERCE/National Bureau of Standards

Laboratory Accreditation:
Future Directions in the United States

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.U57
NO.632
1982

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Laboratory Accreditation:
Future Directions in the United States

Report on the Proceedings of the NBS Workshop
on Laboratory Accreditation held at the
National Bureau of Standards, Gaithersburg, MD

November 16-17, 1981

John W. Locke, Editor

Office of Product Standards Policy
National Bureau of Standards
Washington, DC 20234

U.S. DEPARTMENT OF COMMERCE, Malcolm Baldrige, Secretary
NATIONAL BUREAU OF STANDARDS, Ernest Ambler, Director
Issued March 1982

Library of Congress Catalog Card Number: 82-600525

National Bureau of Standards Special Publication 632
Nat. Bur. Stand. (U.S.), Spec. Publ. 632, 172 pages (Mar. 1982)
CODEN: XNBSAV

U.S. GOVERNMENT PRINTING OFFICE
WASHINGTON: 1982

For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402
Price $6.50
(Add 25 percent for other than U.S. mailing)

FOREWORD

The National Voluntary Laboratory Accreditation Program (NVLAP) of the U.S. Department of Commerce (DOC) was initiated as a result of requests from the private sector over 10 years ago. As a voluntary program, the fundamental operating policy of NVLAP is to publish requests for programs or procedural changes in the *Federal Register* for comment, to hold public hearings or workshops, and to assess and respond to all comments from the public and private sectors. The Department's programmatic decisions are developed by consensus among interested parties within the framework of Federal Government goals and objectives.

When representatives of the American Council of Independent Laboratories (ACIL) suggested that NVLAP significantly change its procedures from the accreditation of laboratories to the accreditation of systems for accrediting laboratories, they were urged to present their suggestions in writing. ACIL was joined in this request by the American Association for Laboratory Accreditation (AALA). Letters from both of these organizations were published in the *Federal Register* (46 FR 40785, dated August 12, 1981). Representatives from these organizations and other interested parties were invited to assist in preparing the agenda for a workshop at which the key issues could be explored.

Written comments were requested both before and after the workshop.

The workshop program, as stated in the brochure inviting all interested persons to attend, was developed around the following key issues:

- Whether the DOC should abandon its present role and substitute in its place a program to accredit organizations which, in turn, would accredit private sector testing laboratories.
- What, if any, additional measures should be taken to assure that an effective U.S. presence remains in international laboratory accreditation activities, including bilateral arrangements.
- What action, if any, can be taken by the private sector and/or the Government to reduce the proliferation of inspections and paperwork arising from duplicative accreditation activities within the United States.

These proceedings document all relevant communications, in the spirit of openness which has been fundamental to NVLAP operations. Summaries of the proceedings and comments after the proceedings are presented in Parts 1 and 2. The formal papers are presented in Part 3, formal comments at the workshop in Part 4, and all letters received in Part 5.

Opinions expressed by authors who are not employees of NBS do not necessarily reflect the opinion of NBS and the content and quality of their papers are the responsibility of those authors. Trade names and trademarks shown in this volume are in no sense an endorsement or recommendation.

John W. Locke
Proceedings Editor
March 1, 1982

EXECUTIVE SUMMARY

In his keynote address at the start of the workshop, Dr. Ernest Ambler, Director of the National Bureau of Standards (NBS), said, "I hope we can formulate a rational, responsive set of proposals that serve the nation in this field of laboratory accreditation." Further, he indicated that these proposals must come within the framework of NBS policy and funding guidelines. The findings in this Executive Summary evolved from a consensus* of participants at the workshop and all other interested parties who responded in writing.

Findings:

1. *There is a need for laboratory accreditation.* The growth in the number of accreditation systems and the statements presented by a majority support this view.
2. *NVLAP should not abandon its present role in accrediting laboratories.* There was little support for the AALA proposal as presented, although about one-fourth of opinions suggest that the accreditation of laboratories should be a private sector function.
3. *Coordination of accreditation activities at the national level is desirable.* The AALA proposal itself suggests that NVLAP perform a portion of this role, and although there is no consensus on the AALA proposal, there is a consensus on the need for some form of national coordination.
4. *NVLAP involvement in international laboratory accreditation activities should continue.* This involvement should include more emphasis on coordination with public sector and private sector laboratory accreditation systems in the United States.
5. *There is no single, best way to accredit laboratories.* Laboratory users and certifiers prefer accreditation based on the competence of laboratories in testing specific products. Laboratories organized to do only one type of testing (such as concrete) appreciate the rigor of an accreditation system designed for testing that product. Multipurpose laboratories cannot efficiently use accreditation systems which focus only on specific, narrow areas of testing. A national accreditation system should be able to accommodate the needs for both a narrow and broad approach to accreditation.
6. *Both national and international organizations demonstrate that accrediting laboratory accreditation systems is feasible.* The papers in Session 4 describe major international accreditation and certification systems which recognize laboratories in other countries, based on use of identical test methods and uniform laboratory assessment procedures. Other agreements between national systems demonstrate that mutual acceptance of accrediting systems with somewhat different operating procedures can be achieved.

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*Consensus is defined as more than a simple majority but not necessarily unanimity of opinion of all interested parties responding.

PROPOSAL FOR ACTION

Presentations and comments during the workshop and written comments since the workshop do not warrant an immediate drastic change in the current NVLAP operations. The consensus, as identified in the Executive Summary, does point to the need for more coordination among all interested parties. To accomplish this, the National Bureau of Standards will support the following actions:

1. *Formation of a Quasipublic National Laboratory Accreditation Council (NLAC).* This council, initiated and managed by the private sector, should have participation from government agencies, professional societies, and certification systems which accredit laboratories. It might be organized under the auspices of a national coordinating body, such as the American National Standards Institute or the National Research Council of the National Academy of Sciences, or as an independent body which could take the form of an association or conference. This council would have the following objectives:
   - Provide forums for written and oral exchange of information on all levels of accreditation in the United States;
   - Develop criteria for comparing or evaluating laboratory accreditation systems;
   - Encourage the recognition of laboratories among laboratory accreditation systems;
   - Encourage use of existing laboratory accreditation systems where new needs arise;
   - Foster consolidations of existing laboratory accreditation systems; and,
   - Develop a basis for reciprocal recognition of laboratories among national and international systems.
2. *Revision of NVLAP Procedures and Improving NVLAP Operations.* NVLAP, over the next several years, should:
   - Revise and simplify procedures, based upon the considerable operating experience gained to date;
   - Form an advisory committee to regularly review and comment on NVLAP operations;
   - Encourage more active participation of the private sector in simplifying the NVLAP procedures for assessing laboratories;
   - Implement bilateral and multilateral agreements with other national and international laboratory accreditation systems to recognize the competence of each system's accredited laboratories;
   - Promote the national and international recognition of U.S. accredited laboratories;
   - Support the organization of the National Laboratory Accreditation Council; and,
   - Reassess periodically the relationship between NVLAP and the private sector.

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Part I

SUMMARY OF WORKSHOP PROCEEDINGS*

Theodore R. Young, ***Consultant***
5016 Euclid Drive, Kensington, MD

INTRODUCTION

On November 16-17, 1981, the National Bureau of Standards (NBS), an agency of DOC, conducted a Workshop on the Future Direction of Laboratory Accreditation in the United States. As stated in the program announcement, the workshop's general purpose was ". . . to provide a public forum for the expression of views upon which recommendations could be developed to bring about a desirable and effective distribution of responsibilities between the government and private sectors in the area of laboratory accreditation." The impetus for the workshop came from related requests received by DOC from the American Council of Independent Laboratories (ACIL) and from the American Association for Laboratory Accredditation (AALA), ". . . to change the NVLAP procedures in order that NVLAP's laboratory accreditation activities would be transferred to the private sector and DOC's role would be limited to that of an accreditor of accreditation systems." A second specific purpose was to provide a public forum for consideration of the growing importance of laboratory accreditation to international trade.

The workshop was organized according to the program description shown in appendix 1 of these proceedings, with five sessions interspersed with discussion sessions. In each session, oral presentations or summaries of formal invited papers contained in part 3 of these proceedings were presented to generate questions and discussion from attendees. The questions and discussion periods were taped and transcribed. Opportunity was also provided for attendees to present formal written statements. These formal statements are included in part 4.

This summary of the workshop proceedings draws from the formal papers, oral presentations, and the oral and written comments at the workshop.

THE WELCOMING ADDRESS

(the relevant paper(s) can be found on page 22)

In his welcoming address, Ernest Ambler, director of NBS, defining laboratory accreditation as "a formal recognition that a testing laboratory is competent to carry out specific tests or types of tests," indicated its economic significance in promoting domestic and international trade. Noting that NBS has statutory responsibility for the Nation's measurement system, Ambler mentioned NBS resources and attributes in support of laboratory accreditation. He observed that government should work closely with the private sector in the public interest, noting that the way for government to increase effectiveness is through close cooperation with the private sector. He presented a number of examples of how NBS has done this in the past. Ambler welcomed the workshop attendees to help define areas in laboratory accreditation for more effective cooperation between NBS and the private sector and expressed the hope that a rational, responsive set of proposals could be formulated to serve the Nation well in the field of laboratory accreditation.

BACKGROUND OF U.S. LABORATORY ACCREDITATION

Accreditation and Certification (page 24)

Baron Whitaker, in his paper, "Meaning of Accreditation and Certification," referenced proposed definitions for "laboratory accreditation" and "conformity certification" expected to be adopted by the International Organization for Standardization (ISO) and the International Laboratory Accreditation Conference (ILAC). "Laboratory accreditation" is defined as "a formal recognition that a testing laboratory is competent to carry out a specific test or specific types of tests." Thus it is clearly evident that laboratory accreditation is oriented and limited to assessing testing competence. Whitaker observed, however, that laboratory accreditation systems are not uniform.

"Conformity certification" is defined as "the action of certifying by means of a certificate of conformity or mark of conformity that a product . . . is in conformity with specific standards or technical specifications." Whitaker noted that product certification, being oriented to product conformance vis-a-vis testing competence, is (should be) also concerned with the materials, assembly, design, and features of production that relate to the manufacture of a uniformly complying product.

Confusion in the meaning of product certification and laboratory accreditation exists at both the national and international levels; Whitaker pointed out that during our discussions we must remember that certification refers to the conformance of a product delivered to a consumer in the market place. Accreditation refers to the competence of a laboratory to perform tests. Charles Hyer, in his paper, "Status of Laboratory Accreditation in the United States," seems to agree. Hyer noted that laboratory accreditation as it relates to product certification is not a "mutually inclusive or exclusive term." He stated that an accredited testing laboratory affiliated with a product certification system may or may not validate products for certification. In fact, the certifying authority may be neither a laboratory nor accredited.

Assuming that assurance that a product conforms to a standard is an important ingredient in many domestic and international trade transactions, Whitaker identified discrete differences between laboratory accreditation and stringent product certification in regard to fulfilling the need for such product assurance. He concluded that laboratory accreditation does not provide needed assurance in situations such as: where conformance to a product standard relates to aspects other than testing; where proficiency testing required by accreditation does not specifically demonstrate ability to test the product (a likely situation where complex technical products are involved); and where there is need for each conforming product to be publicly identified.

Whitaker concluded that laboratory accreditation can serve many needs for product assurance where products are bought and sold by lots or batches on the basis that they pass prescribed laboratory tests. When purchasers or regulators need assurance that ongoing production complies with all requirements of specific standards, together with a mechanism for identifying such complying production, then product certification that includes concern for factory quality control is needed.

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*Prepared under contract.

History of Laboratory Accreditation (page 28)

Theodore Young, in his paper "History of Laboratory Accreditation in the United States" utilized the publication, "Principal Aspects of U.S. Laboratory Accreditation Programs"* to characterize historical trends of some 70 programs dating from 1932.

Young classified the programs into two types based upon their motivation, and describes characteristics, trends, and impact of each type. One type of program is motivated by product certification needs. The principal parties served by such programs are the motivators and the laboratory users who seek from test data produced by accredited testing laboratories evidence of conformity of their products to standards. The motivators include Federal, State, and local product regulators, product certification programs, procurement officials, international trade negotiators, and trade association product enhancement programs. Young estimated that this type of accreditation program is experiencing an exponential growth rate in recent decades.

The other type of accreditation program develops from the need to assure that qualified testing services exist to serve the public and the government. Motivations for this type of program are directed toward the laboratories rather than the laboratory users. Entities such as public health laboratories, environmental laboratories, clinical laboratories, and those providing product testing services for the public or government are motivated to obtain accreditation (or license) by government regulations or procurement protocols for testing services and by peer group qualification programs. Participation of laboratories in such programs is often mandatory. Young noted that this type of accreditation program shows an approximately linear rate of growth since 1960.

Young observed that most of the programs accredit less than 100 laboratories; a few accredit as many as 500 laboratories. However, accreditation services can be provided on a large scale. This is demonstrated by the program of the Health Care Finance Administration (HCFA), which accredits 13,000 clinical laboratories serving Medicare and interstate commerce.

Observing that NVLAP and AALA, initiated in 1976 and 1978 respectively, were both established to serve general needs for laboratory accreditation, Young noted that each program could have difficulties in meeting all the needs exemplified by those accreditation programs reviewed. AALA's intent to accredit laboratories on the basis of broad technical disciplines or narrower subdisciplines may not meet the requirements of users who need laboratories accredited for competence related to specific test methods and product specifications. On the other hand, NVLAP's requirement that accreditation be referenced to particular test methods may not meet the needs for competent laboratory services that cannot be characterized by a set of test methods or that involve a set of test methods so large as to make it impractical or unreasonably costly for laboratories to achieve accreditation.

Present Status of Laboratory Accreditation (page 36)

In his paper, "Status of Laboratory Accreditation in the United States," Charles Hyer commented on his preparation of the report, "Principal Aspects of U.S. Laboratory Accreditation Programs," and described recent activities of three of the accreditation programs reported: the NVLAP, AALA, and the IECQ systems.

NVLAP, in developing its new accreditation programs, provides an opportunity to help resolve technical issues relevant to the test methods involved. Hyer observed that only a small percentage of the 100 laboratories accredited by NVLAP offer testing services for fees. He believes that this meager participation by commercial laboratories is a temporary situation that will change as NVLAP programs increase and as commercial laboratories find the need for and value of such accreditation.

Observing that AALA's purpose is to serve overall needs for laboratory accreditation rather than limited specific areas such as those related to product certification, Hyer stated that AALA programs now relate to three discipline areas (electrical, chemical, and construction material testing). He noted that AALA has offered accreditation for subdisciplines within these, making such accreditation more meaningful. Hyer mentioned that some 40 organizations have shown interest in AALA's accreditation, and that commercial laboratories have shown particular interest. All of the seven laboratories now accredited are commercial laboratories, and six are members of the American Council of Independent Laboratories.

Speaking of the IECQ Quality Assessment System for Electronic Components, Hyer observes that this product certification effort of national scope and international effect has appointed Underwriters Laboratories, Inc., to serve as its national supervising inspectorate. A task of the inspectorate is to accredit participating manufacturers' laboratories and those commercial laboratories employed by such manufacturers. Mentioning the potential significance of this system, Hyer noted that the system's accreditations could possibly gain government recognition if it uses appropriate standards. Further, he indicated that the system will serve the electronics industry, which has had a de facto laboratory accreditation program for years; that the syseem, being the first international quality certification system, will, if successful, become the standard for worldwide certification programs; and that, for the system to succeed, reliable performance of testing laboratories will be essential.

As an example of newly established accreditation activities, Hyer mentioned the recent program of the Institute of Electrical and Electronic Engineers. Its purpose is to accredit environmental testing of safety equipment used in nuclear power stations. Accredited testing will be required by NRC, which will use the program as a means of reducing multiple audits.

Hyer said he believed that near future trends in laboratory accreditation will be governed by economics. Reduced government budgets will force more reliance on the private sector. He estimates that some 50,000 laboratories currently require one or more forms of accreditation. Over 2,500 laboratories requiring multiple accreditations have been identified; some, such as large commercial nondestructive testing laboratories, require as many as 100 accreditations.

Noting that opportunities for consolidation of laboratory accreditation activities will be viewed differently by various interests, Hyer asserted that the market for accreditation will demand cost-effective programs. He observed that existing accreditation programs will extend their scope to serve developing needs. Duplicative accreditations now justified on the basis of national, State and local jurisdictional concerns need to be eliminated. Hyer concluded that the worldwide need for assurance of product quality, by itself, provides economic justification for increased use of laboratory accreditation.

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*Referring to this publication in his workshop presentation, Charles Hyer, its principal author, stated his belief that it is the most informative source presently available on government and private association programs dealing with assessment of testing, examination, and inspection services. However, Mr. Hyer advised that the selection of programs for the publication was somewhat arbitrary, favoring those related to product verification and certification, and that the summary may be incomplete due to economic constraints of the study.

An attendee inquired about the future of NVLAP and its current and future financial prospects. Stanley Warshaw of NBS advised that government programs, including NVLAP, were currently operating under a continuing resolution until December 1981. Thereafter, NVLAP funding would depend upon congressional action on the fiscal year 1982 budget request. However, Warshaw noted that direct costs of accreditation under operational programs are supported by fees charged to participating laboratories. Future alternatives for NVLAP, now under consideration, include working with, or in support of, the private sector in the area of laboratory accreditation.

In response to a question regarding who might use AALA's accreditation, Hyer indicated that he did not know of any organization that currently requires AALA accreditation. He estimated that the future would depend upon diminishing ability of existing programs to fund their own programs and the ability of AALA to tailor its programs to meet the existing requirements.

Another attendee inquired whether AALA plans accreditation of environmental testing laboratories, such as those required by EPA's NPDES program. Louis Rossi of AALA indicated that AALA has no program for environmental testing except wherein its program for chemical testing would apply.

INTERNATIONAL TRADE IMPLICATIONS OF LABORATORY ACCREDITATION (page 40)

Charles Hyer (above) noted in his paper that opportunities will exist in the future for laboratory accreditation to meet the needs of international trade. Laboratory accreditation that would allow U.S. laboratories to be on-site approval agencies for foreign procurement activity could be an important adjunct to international trade.

The General Agreement on Tariffs and Trade (GATT), and in particular, its Agreement on Technical Barriers to Trade, popularly called the Standards Code, provide challenges to our national federated standards system. In his paper, "International Trade Implications of Laboratory Accreditation," Donald Abelson, director of Technical Trade Barriers for the Office of the U.S. Trade Representative, noted that the Standards Code contains obligations on GATT treaty partners pertaining to development of standards, conformity testing, and final certification of products. The code is applicable to industrial and agricultural products; however, government purchasing specifications and inhouse standards are exempted.

Abelson listed several provisions of the Standards Code, which require that: product standards must utilize performance criteria whenever possible; access must be provided to national and regional certification systems; and imported products are to be tested in the same manner as domestic products. The code recognizes that the mutual acceptance of test methods and data can significantly liberalize trade. From his experience in handling trade problems, Abelson claimed that the reciprocal acceptance of tests and test data will be the most significant technical issue in future Standards Code discussions, requiring priority attention of U.S. Government experts.

Abelson noted that bilateral discussions concerning specific products with key Standards Code signatories, inevitably address reciprocal acceptance of test data and the accreditation of laboratories. Observing that there is a problem for the United States in responding to foreign requests for "official" approval of test results, he commented that the United States is not eager to provide such official guarantees. Abelson pointed out that current U.S. policy is to encourage foreign governments to accept the U.S. standards system, which operates "smoothly" without Government interference. He noted various ways of serving product assurance needs that the United States successfully supports as alternatives to providing Government approvals of products in international trade. The United States:

- Favors the development of international standards of Good Laboratory practice, such as those being developed by OECD;
- Sees promise in national voluntary laboratory accreditation programs, such as NVLAP, if they can develop the required scope of product coverage;
- Encourages foreign governments to recognize the American system of private laboratories independent of manufacturing;
- Claims that its legal system, particularly its product liability laws, guarantees product reliability better than could be done by a Government agency; and,
- Supports establishing a framework for international accreditation of laboratories that does not rely heavily upon official Government sanction of laboratories.

In regard to U.S. reliance upon its national federated standards system, Abelson noted that we differ from most of our foreign competitors, where Government intervention is common. However, the United Kingdom has an active private sector standards community that enjoys a degree of recognition by the Government. Also, the United Kingdom is experienced in dealing in reciprocal trade arrangements within the Common Market. Thus, recent U.K. actions in establishing its national laboratory accreditation system are of interest. Dr. P. G. Forrest, in a statement presented to the workshop (see part 4 of these proceedings) noted that the National Testing Laboratory Accreditation Scheme (NATLAS), the U.K. counterpart to NVLAP, was recently established as a Government operation. The development of NATLAS was guided by a steering committee of representatives of laboratories, their customers, and organizations that accredit laboratories. Considering whether NATLAS should accredit laboratories or organizations that accredit laboratories, the United Kingdom concluded that laboratories' results would be more readily accepted overseas if laboratories were directly accredited by NATLAS. In addition, a centralized system using a single set of regulations and criteria would make it easier to negotiate mutual recognition with other national laboratory accreditation schemes.

Relating experiences in marketing tractors internationally, Frank Walters of the John Deere Company, in his presentation to Session III of the workshop, said that our Government agencies and industry need to work together. We must operate in the most efficient manner, if the United States is to remain competitive. Because of attitudes of many importing countries, some international trade functions can be accomplished more efficiently by Government; these functions relate to authoritative testing/inspection of products for compliance to regulations.

In response to a question, Abelson indicated that Australia intends to sign the Standards Code. It has not done so due to problems arising from their Federal-State relationship. In response to an inquiry about problems in trade agreements deriving from reference to international, rather than U.S., standards. Abelson said that the United States is obliged to use appropriate international standards and to participate in appropriate international standards activities. Abelson stressed the importance of our participation in developing international standards that we can use and in resisting block voting efforts of groups of countries to put our technology at a disadvantage.

Asked for recommendations regarding "rational or due process" procedures that might be implemented to improve our acceptance by foreign interests, Abelson pointed out that the United States has systems, such as the ASME system, that are in fact international. He recommended that the United States strive to develop similar systems as efficiently as it can so other countries will be obliged to use them. Responding to a question as to whether the international trade needs for laboratory accreditation have become sufficiently general to warrant NVLAP providing accreditation programs of a broader base, Abelson indicated that needs are still very product specific.

NEED FOR LABORATORY ACCREDITATION

Purposes of Accreditation (page 43)

In his overview paper, "Purpose of Laboratory Accreditation," John Locke described the findings of ILAC's Task Force C Report as adapted to the situation in the United States. Published in ILAC/80 Proceedings, this report describes the need for and the objectives, effects, and consequences of laboratory accreditation. Locke noted that the report reflects some 30 years' operating experience of the Australian program, modified by experiences of participants from other countries operating more recently developed or developing systems.

Noting that the need for laboratory accreditation is demonstrated by the large group of programs existing in the United States, Locke said such programs serve those needs:

- Private sector purchase of components and subsystems
- Private sector certification programs
- Government purchasing
- Government funding involving programs that provide financial support to the public
- Government regulations requiring premarket testing by accredited laboratories
- Government certification of products

To summarize these activities, Locke related these needs to saving money; reducing contractor risk; assuring product adequacy, performance, and safety; enhancing industrial and professional image; and providing quality assurance for laboratory management.

Locke noted an additional need served by laboratory accreditation, namely, that manufacturers need qualified laboratories for product development, quality control, and failure investigations, or need to have their own laboratories recognized as being so qualified. Noting that a large number of accreditation systems are evolving, Locke cited the developing need to consolidate the examination of laboratories to reduce costs and minimize disruption of productive laboratory work.

Claiming that the objectives of almost all laboratory accreditation systems emphasize correction of deficiencies rather than denial of recognition, Locke listed the following specific objectives that accreditation systems may have:

- Promotion of good testing practices and validity of test data;
- Improved efficiency in use of test facilities and reduction of need for redundant testing;
- Public credibility and status rewards for competence;
- Effective support for international trade; and,
- Objective information on laboratory practice, including feedback to standards developers.

Laboratory accreditation is affecting and benefiting laboratories, their users, and the community at large. Locke stated that the management and staff of participating laboratories are now more aware of requirements for calibrating equipment, documenting methodology, recording and reporting test data, and participating in interlaboratory proficiency tests. Users are placing greater reliance on test reports, reducing their demands for duplicate testing. The community is more aware that weaknesses can exist in testing services and is becoming more selective in its use of laboratories. Laboratories benefit by upgrading their capabilities and having available a reference basis for assuring their own quality and improving the marketability of their services. Laboratory users benefit from improved quality control and markets for their products. The community benefits by having a better and more reliable testing resource. Additional benefits for the United States are to be obtained if international markets can be opened for accreditation systems. Locke claimed there is a need for an accreditation system or systems to focus on international reciprocity in acceptance of test data produced in exporting countries.

In conclusion, Locke pointed out that there are costs associated with the benefits of accreditation. There may be direct costs to the laboratory for the accreditation service itself and indirect costs resulting from meeting calibration, proficiency test, and procedural documentation requirements. Locke suggested that such indirect costs would apply to any well-run laboratory and little should be attributed to accreditation activities. He noted that the costs of accreditation, when passed on to the laboratory user, can be substantial or trivial depending upon the laboratory's test volume.

There was an inquiry from the audience as to whether any accreditation systems now address or plan to address the important subject of sampling and sample preparation. Locke said that the accreditation criteria do not address sampling requirements directly, and that these requirements are considered when addressed in the referenced standards and test methods. It was noted from the floor that EPA's program for drinking water laboratories and NVLAP's concrete program pay due attention to sampling requirements.

An attendee, commenting that many laboratories enjoy "Federal credibility" even though the NVLAP accreditation may cover different test methods of varying sophistication, inquired as to how NVLAP differentiates between sophisticated and basement operations. A NVLAP assessor replied that it is quality and reproducibility of test data reaching the user that is important, rather than size of the laboratory. Another question related to how NVLAP assures such reproducibility on the basis of criteria used. Locke said that the usual operational scope of accreditation systems, including the Australian program, is recognition to do specific tests and specific tests only. These programs are trying to recognize the competence of laboratories to do routine testing for ordinary products. One should not extrapolate the capability of the laboratory beyond those specific findings. An attendee reminded the workshop that NVLAP originally proposed accrediting laboratories for disciplines, but changed to a product basis because of public comment. Currently, NVLAP has established alternative procedures whereby the private sector or Federal agencies can, by consensus or legal authority, find a need for an accreditation program and develop its accreditation criteria. If the private sector or a Federal agency can find a need and develop the necessary criteria, NVLAP can establish accreditation programs of broader scope, such as disciplines.

Noting the discussion pertaining to international aspects of laboratory accreditation, another attendee inquired about what accreditation systems such as NVLAP are doing to encourage State and local government recognition, and suggested that more effort may be needed in this area. A question from the floor asked how laboratory accreditation could fill State and local needs for product assurance (certification). Ted Pritsker, a panelist, did not see a real difference, except that accreditation and certification are consecutive features of an overall assessment that also includes engineering evaluation of test data. John Locke observed that State authorities have various needs; one is for product test data provided by programs of the Code Officials' organizations. He noted that NVLAP will continue to emphasize that its scope concerns only the competence of laboratories. However, persons using laboratories are free to use the accreditation program as needed to serve their requirements. Charles Hyer suggested that a consensus was not needed on the need for accreditation of services for testing, sampling, design engineering, certification, etc. Accreditation programs will be established if they are economically viable and supported by significant laboratory users that want the assurance provided.

Needs of the Independent Laboratory
(two papers, pages 46 and 52)

Earl Hess, in his paper, "The Need for a Practical Laboratory Accreditation Program from the Perspective of a Small Multi-Discipline Independent Laboratory," observed that a laboratory accreditation system that ensures technical credibility of analytical laboratories is indeed the "primary standard" on which product quality measaurements are based. Hess said he believed that his laboratory's diligent implementation of an internal quality assurance program is incomplete until exposed to scrutiny by a qualified outside source. For instance, regardless of any national recognition to be derived, he said he believed his laboratory's accreditation by AALA for the chemical discipline was worth the entire cost and effort involved. However, narrow-gauge accreditation programs, such as those that are product-by-standard oriented, are impractical for small multidiscipline laboratories. Despite experience over the years with a "plethora" of such narrow-gauge programs, he estimated that 75 percent of his laboratory's work was still not covered by these specialized accreditation programs. Even if coverage was available, the number of specialized accreditations needed would be excessive, cumulative accreditation fees would be prohibitive, and attendant paperwork and lost productivity would be intolerable. Except for their impracticality for multidiscipline laboratories, Hess did not fault product-oriented accreditation programs. He noted that NVLAP had developed valuable criteria and procedural materials that have advanced the state-of-the-art, and had enhanced appreciation of the need for and worth of accreditation. He said, however, that NVLAP's awakening the public to the need for accreditation without supplying a program to serve the overall need had been a disservice to laboratory activities outside the scope of NVLAP's accreditation. Hess's first conclusion was that the only national laboratory accreditation system both practical and efficient is accreditation by discipline.

Hess's second conclusion was that an effective national system for laboratory accreditation must be based in the private sector. He claimed that laboratory accreditation is not inherently governmental any more than is standards development, and that a consensus supports the government leaving the provision of standards to qualified private sector bodies. Hess noted that significant private sector interests and accreditation programs exist that should be assisted and relied upon by government to perform accreditation functions. He stated that AALA is one such private sector body. Hess observed, however, that the U.S. Government must maintain responsibility for laboratory accreditation in the international arena. As a result of GATT and the activities of the International Laboratory Accreditation Conference, to be credible to our trading partners, the Government must represent U.S. interests in laboratory accreditation.

In addition, Hess pointed out that Government's reliance on private sector services would be consistent with long-established Government policy. Stating support for the the ACIL and AALA proposals, Hess concluded that NVLAP should gradually withdraw from accreditation of laboratories and become the accreditor of private-sector accrediting systems and serve as the U.S. international liaison in laboratory accreditation.

Hess concluded by identifying specific advantages laboratory accreditation on a discipline basis to the general public of the users of laboratory services, and the laboratories themselves.

Hess was asked why he hadn't requested a NVLAP program to serve the needs of his laboratory, particularly a laboratory accreditation program under NVLAP alternative procedures "Part 7c" established in October 1978. The alternative NVLAP procedures might allow establishment of an accreditation program of a broader than product scope. Hess replied that he could not accept a program on a product-by-product basis, as required by the original NVLAP procedures, and by the time the alternative procedures had been introduced he had decided to seek the services of AALA.

Another attendee asked Hess how AALA assures credibility for various subdisciplines when it accredits laboratories for a whole discipline, such as chemistry. Wouldn't competitors, equally accredited but having lesser qualifications in some subdisciplines, have a competitive advantage? Hess replied that AALA's accreditations for disciplines are supplemented by accreditations for subdisciplines including the specific products in such subdisciplines. A laboratory entering a new field (within the discipline) must advise AALA and demonstrate its capability in order to be listed by AALA. Asked whether AALA accreditation, in effect, does list test methods and products covered, Hess said that AALA accreditation for disciplines provides an umbrella under which the credibility of a laboratory can be established (staff ability, equipment inventory, quality control program). To supplement the general accreditation, his laboratory would be glad to perform, at a client's request, a proficiency test on a blind sample to demonstrate ability to serve a specific need.

Another attendee asked if AALA provided an appeal procedure for laboratories subject to losing their accreditation. The attendee also wanted to know if AALA requires laboratories to notify clients if they lose qualifications necessary for renewal of their accreditation. Hess stated that accredited laboratories have an ongoing responsibility to notify AALA of significant changes. For reaccreditation, AALA requires a yearly update of information and biennial site visitations. For significant changes, site visits may be required at any time. Hess believed that AALA had an appeal procedure, but could not comment on its details.

Another attendee asked if there would be a benefit in establishing a peer group of testing laboratory interests having concern for accreditation. Noting that there is a sizeable population that supports accreditation only for serving particular needs, the attendee observed that the major issue may not be a product versus discipline approach; the problem may be an inadequate definition and description of needs. A peer group of accreditation interests could respond to this problem. Hess indicated that he would support a broadening of AALA to include not only commercial and inhouse laboratories but also government agencies and other users of laboratory services.

William Levelius, in his paper, "Independent Laboratory with Many Separate Laboratory Locations," identified and described the major components and subelements that should be included and detailed in the corporation's quality assurance manual. Noting that the major components of the quality assurance program are the essential elements contained in regulations for the nuclear energy industry (10 CFR 21, Appendix B), he listed the major components of a quality assurance program.

Levelius observed that the corporation's quality assurance program should be controlled by a department in the executive offices reporting directly to management. Its duties should include program writing and revision, maintenance of corporation calibration standards, calibration of certain equipment, system operation review, and internal audits. In addition to continuous desk audits, the system should require yearly indepth audits and spot audits by executive management during regular visits to the branches. A most important control should be a stringent followup on customers' complaints.

Noting that a corporate quality assurance program and an accreditation activity are similar in their work effort, Levelius pointed out that a corporate quality assurance program has the advantages of being continuous and being conducted by personnel familiar with the corporation's testing business. An accreditation program that requires on-site examinations of the corporation's branches is duplicative, creates an excessive amount of redundant paperwork, and takes an inordinate amount of time of both the laboratory and the accreditor.

From the viewpoint of one of several hundred multilaboratory corporations, Levelius concluded that an accreditation system should consider blanket accreditation of such corporations in lieu of individual accreditations of each branch. He based this conclusion upon the assumption that the multilaboratory corporation must have an operational corporate quality assurance program.

William Levelius's second conclusion was that accreditation can benefit the laboratory industry only if properly designed and administered. A system that would replace the multitude of existing accreditation programs needs to be flawless, satisfy all needs and desires, and be mandated by law. He listed several aspects that should be of concern:

- Prohibitive costs of accreditation to small laboratories;
- Intolerable overall cost of accreditation on a product by product basis;
- The capability and impartiality of assessors;
- Flexibility beyond basic requirements to allow laboratories to tailor methods to meet their needs; and
- Recognition that national standards sometimes contain impossible or impractical test requirements—the exposure to litigation that accreditation for meeting such requirements might entail.

An attendee questioned Mr. Levelius concerning Pittsburgh Testing Laboratories' inhouse quality assurance program. What followup process is conducted if a current audit of one of the laboratories provides evidence that faulty test results were produced since the time of last audit? Levelius indicated that followup depends upon the significance of the error. The audit group reviews the testing log books to see whether or not the error has a significant bearing upon test results issued.

Needs of Manufacturers (two papers, pages 54 and 57)

Speaking for manufacturers, Richard D. Gaynor provided a viewpoint of concrete producers in his paper, "Why Concrete Laboratory Accreditation—Why NVLAP." Noting that concrete producers are responsible for quality of material delivered to the job site, he observed that in the United States the producers do not perform the acceptance testing of their own product. Building code officials, architects, engineers, and contractors, who generally hire concrete testing laboratories, are involved. According to Gaynor, current practices and competitive conditions frequently create conditions for an unacceptably low standard of testing quality. Concrete testing laboratories, requiring modest capital and little scientific knowledge, are often garage operations selected by contractors on the basis of lowest bid. Stating that incorrect testing generally produces concrete strength results that are too low, requiring unnecessary followup investigations of the structure involved, Gaynor estimated that a third of all low-strength test results were due to improper testing.

Noting that accreditation now provides a method for evaluating the capability of producers' quality control programs and concrete testing laboratories, Gaynor said that significant developments in serving the need came with the establishment of ASTM Committee E36, the promulgation of their standard E548 (general evaluation criteria for testing agencies), and the initiation of the Concrete Laboratory Accreditation Program under NVLAP. For the first time in concrete testing, a user of laboratory services can identify and specify the quality of service he/she wants and expects.

In commenting on the issue of whether NVLAP should leave accreditation of laboratories to private sector organizations such as AALA, Gaynor expressed confidence that NVLAP is accessible and can change, improve, and evolve. For example, he noted that NVLAP has been criticized for being too detailed and requiring too much paperwork. However, he observed that NVLAP programs differ. The thermal insulation programs cover many test methods; an applicant laboratory may choose those for which it seeks accreditation. On the other hand, the concrete program covers only a few of a whole book of test methods available, selected because of commercial importance. Gaynor expressed the hope that as the concrete program further evolves, it will not add other test methods based on similar technology and procedures. Gaynor claimed that it is now clear that the benefits to be derived from the current concrete laboratory accreditation program will greatly exceed Government expenditures on the program.

Gaynor expressed several concerns regarding the AALA program. His general concern was that the AALA program is supported by laboratories that would like a simple inspection by peers without specific criteria that can be documented. Although AALA intends to use ASTM E548 for every discipline, Gaynor claimed the real issue was the extent and detail that AALA would employ. Will AALA require proficiency testing programs wherever critical test methods are being assessed? He was also concerned that AALA does not appear to have procedures which allow for comment by the general public, such as those relating to accreditation criteria and accreditation decisions.

In addition, Gaynor wondered whether AALA could assemble the resources necessary to develop an adequate program. He noted that the NVLAP system, designed to be self-supporting, would take some time to achieve this goal. He pointed out that the Australian accreditation program, NATA, relies on its Government for 60 to 70 percent of its funding. He believes that AALA's membership fees are now sufficiently large to inhibit participation of many laboratories. Finally, he questioned AALA's ability to defend a fair but tough accreditation system against legal challenge from a laboratory deprived accreditation. Admitting that NVLAP might be similarly threatened by political pressures, Gaynor suggested that there may be need for both NVLAP and AALA in their presently conceived roles.

Speaking from years of experience with the oil industry, John Grant, in his paper, "Laboratory Accreditation as Viewed by a Manufacturing Concern," concluded that accreditation is necessary and desirable for the independent and commercial testing laboratory community. Although inhouse laboratories should not be denied accreditation services, Grant stated that accreditation for inhouse quality control laboratories of technically advanced manufacturing industries, such as the petroleum industry, had doubtful value and could become an unneccesary burden and expense.

Using the petroleum industry as an example, he pointed out that the work of ASTM and other standardization activities had provided specifications for essentially all petroleum products. Standardized tests and analyses, with precision established by cooperative laboratory testing programs, are available for determining compliance with the specifications. Most petroleum companies have inhouse quality assurance programs including interlaboratory testing programs for their several quality control laboratories. These laboratories usually can receive assistance when needed from the industry's central research organizations. The independence and authority of the quality control laboratories is generally assured by company policy.

Grant observed that excellent inhouse laboratories frequently need to utilize commercial laboratories for specialized analytical work; and that there was a real need for a way of assessing such laboratories. Otherwise one selects laboratories on the basis of personal acquaintance, recommendations of others, society affiliations, or by submission of trial test samples of known composition. These methods are time consuming, expensive, and are subject to mistakes that can be costly. Accreditation of laboratories can simplify the selection process and make it more reliable.

However, Grant expressed concern with the way accreditation systems were developing. There is too much significance attached to academic qualifications, organization, office routine, independence, and integrity. Laboratory performance is what matters. This can be assured with proficiency samples, interlaboratory comparisons, and use of competent and knowledgeable evaluators. In addition, the time and expense of accrediting laboratories must be reduced—an obvious conclusion considering that a laboratory might be called upon by the petroleum industry to perform 500 to 700 different analyses on over 500 different products. Competent and knowledgeable assessors are keys to a successful laboratory accreditation program. Grant concluded that cooperative efforts of all interested parties is necessary to achieve the required systems.

An attendee questioned Grant as to whether the petroleum industry needed accreditation of non-product oriented laboratories, such as pollution control (NPDES) laboratories. Mr. Grant observed that some petroleum companies are doing their own testing whereas many are contracting for this testing. Where Federal or State regulations require accredited testing, the petroleum industry would cooperate to get laboratories accredited as required.

Needs as Seen by an Exporter (page 59)

To illustrate the problems of exporting, Frank Walters used the example of the agricultural tractor. According to Walters, the first problem was to determine the impact of governmental regulations on tractor design. As of 1978, he noted 52 tractor components subject to various requirements imposed by 30 countries. For comparison, Walters observed that the United States imposes only one rule on importers of tractors; that manufacturers self-certify their tractors as meeting OSHA requirements regarding roll-over protective structures. Walters asserted that some alleviation of this export problem was underway in the Common Market but that a major problem still exists.

The second problem facing exporters is the process that Walters called "homologation," which is defined as the premarket testing and/or inspection for compliance with regulations conducted by the importing country's officials. This requirement involves presenting one or a batch of tractors to various foreign testing or inspection authorities for certification prior to obtaining a permit to sell. Depending upon the country involved, the homologation process may take 2 weeks or as long as 18 months. Walters explained that because of this process the manufacturer must either stockpile the product ready for sale or build expensive prototypes in advance of production. Subjective interpretation of the requirements can result in emergency changes in the product design. Walters estimated that a manufacturer may need to build 100 prototypes to gain the necessary certificates to market a new tractor line. Walter noted that EEC's present effort to harmonize requirements includes the homologation process.

Walters observed that because of attitudes of foreign countries, there were international trade functions that could be accomplished more efficiently by Government. U.S. exporters need a homologation process performed in the United States that is acceptable to foreign countries' importing authorities. NVLAP or a form of it is needed to verify laboratory competence to perform the required tests. In addition, exporters need a system where an organization, acceptable to importing countries' authorities, issues documents attesting to review and findings of compliance when test results are found to meet the importing countries' regulatory requirements.

Needs of State and Local Governments (page 61)

Constitutional police powers granted to the States include those assuring healthful and safe buildings and building products, including appliances. Donald Pinkerton pointed out that State and local governments must be assured that a system is in place that provides for a minimum acceptable level of performance, safety and useful life of materials and products. He noted that State and local governments are generally opposed to the concept of self certification, and in some instances must deny the acceptance of new products and technology when recognized standards and test methods are not available. Pinkerton observed that State and local governments make widespread use of product standards, certification, and laboratory accreditation in regulation and procurement activities. Use is prescribed in a number of State laws and local ordinances that vary among jurisdictions, thus burdening both laboratories and product manufactuers.

Citing several existing laboratory accreditation programs dealing with building products, Pinkerton conjectured about problems for building officials should these programs offer different findings in regard to the accreditation of a laboratory. He noted that the intent of the National Conference of States on Building Codes and Standards (NCSBCS) Laboratory Accreditation Program is to use existing accreditation systems when available. NCSBCS is discussing with NVLAP and AALA participation by the States in their programs.

Pinkerton stated the need for:

- A general agreement by all involved parties that a specialized or programmatic voluntary accreditation system is desirable;
- Acceptance throughout the United States of laboratories accredited by the system; and
- Establishment of an advisory council of State and local officials to make Federal Government and others aware of concerns and needs regarding imported building products and appliances.

Pinkerton concluded that a voluntary system acceptable to both the private and public sector must be established if Federal legislation on the subject is to be avoided. He noted that NCSBCS wants to become an equal partner in such a system.

Needs of Federal Regulators (page 63)

Licensees of the Nuclear Regulatory Commission (NRC) are required to measure the radiation dose received by workers (personnel dosimetry), measure the amount of airborne radioactive material ingested by the body (bioassay), and sample the environment for radioactive material content (environmental monitoring). In his paper, "Advantages to the Nuclear Regulatory Commission of Third-Party Laboratory Accreditation Programs," Robert Alexander noted that personnel dosimetry, bioassay, and environmental monitoring all require competent laboratory performance in which NRC must be confident. Because of limitations on NRC's staff and resources, NRC plans to use other laboratory accreditation programs based on performance testing and quality assurance inspection. The plan involves adopting an appropriate consensus performance standard, including quality assurance criteria, and mandating a requirement for use of accredited laboratories after establishment of an operational program by a laboratory accreditation system selected by NRC.

Observing that the plan has been initiated for personnel dosimetry and bioassay utilizing NVLAP, Alexander identified advantages and disadvantages for NRC, for industry, for nuclear workers, and for the public. Advantages for NRC are that NVLAP has the necessary legislative authority, liaison staff, accrediting experience, proficiency testing, inspection processes, and criteria components to serve NRC requirements.

NRC supplies minimal staff, no long-term financial commitments, and is not involved in possible disputes. Other government agencies can use these programs without funding commitments. Disadvantages and potential problems of using NVLAP are that NRC must fund development of the accreditation programs and costs of radiation sources and the approach may be viewed as an expansion of Federal regulation over industry. Problems will arise if an inadequate number of laboratories qualify, and for an interim period NVLAP will need to rely upon the NBS Center for Radiation Research for technical support.

For industry, laboratory accreditation programs provided by NVLAP will promote better quality control, accuracy, and credibility of test results leading to better laboratory performance and reliability and fewer customer demands for their own assessments of laboratory capability. Accreditation will provide laboratories with advertising advantages and will allow them more time than a regulatory action to correct problems and deficiencies. Disadvantages to industry relate to the initial and continuing costs of maintaining accreditation, the possible consequences of losing or failing to achieve accreditation, and the possible reluctance of accredited laboratories to introduce new innovative techniques.

Advantages for affected nuclear workers will be more assurance that employers are using competent laboratories, and producing accurate and verifiable measurement results, appropriately documented and maintained as required by NVLAP criteria for accreditation. This may assist litigation and is particularly important in assessing the long-term biological effects of low-level radiation. A disadvantage to the worker is that the employee might lose credibility should a laboratory lose its accreditation. In addition, employers that voluntarily provide radiation protection services for their employees might terminate such laboratory services if costs increase.

Alexander observed that greater public confidence in laboratories resulting from NVLAP programs could be damaged if large numbers of laboratories were to fail to achieve accreditation. In addition, he noted that the public will indirectly pay the costs of these accreditation programs. Alexander concluded that such accreditation programs will contribute to U.S. radiological health protection at a cost that is small when compared to the benefit to be derived.

Needs of the Consumer (page 65)

Consumers' interest in laboratory accreditation is presently secondary to their interest in product standards and certification. David Swankin defined "consumer" as the end-use buyer, not others such as industrial buyers and users. Consumer interest is based on the widely accepted consumer rights first introduced by President Kennedy: the right to be informed, the right to choose, the right to safety, and the right to be heard.

Regarding the consumers' right to be informed, Swankin raised the issue of whether a laboratory accreditation system should allow laboratories and laboratory clients to advertise a laboratory's accredited status to the consuming public. Whereas some claim that such advertisements would be interpreted as product certification, others claim that it can provide useful information to end-use consumers. Swankin said he believed that laboratory clients should not be allowed to advertise that consumer products have been tested by an accredited laboratory. On the other hand, a laboratory should be allowed to advertise to potential clients that it is accredited.

As to the consumers' right to choose, Swankin based his position on the general proposition that monopolies ill-serve consumers. Therefore, consumers are better served if product suppliers, particularly small businesses, have available quality testing services of competing accredited laboratories. This is because monopolies can lead to unjustified high prices which are passed to the consumer.

Swankin observed that accreditation programs should be establised only when needed. They must be fair and unbiased, and they must be perceived as such. They must be administered so that everyone is not always accredited. If everyone is accredited, it is time to reconsider the need for accreditation.

Laboratory accreditation can enhance the consumers' right to safety. Swankin noted that laboratory accreditation systems have the opportunity to exert an influential role in upgrading safety standards relied upon by consumers. An accreditation body has the prestige, influence, and knowledge to identify shortcomings in safety standards for the standard developers. This public service would enhance the prestige of laboratory accreditation systems.

Important to the consumers' right to be heard is the consumers' interest in the currently popular issue—the respective roles of the public and private sectors. However, Swankin did not see the public versus private sector aspect of the NVLAP/AALA question as being the main issue. Either system could administer a laboratory accreditation program well or poorly. Swankin described the NVLAP/AALA question as an unnecessary "turf" battle that should be avoided, as it diverts attention away from the real effort that is needed.

Swankin claimed that the consumer is best served by laboratory accreditation systems with the most integrity, the best quality, the most efficient and cost effective processes, the best accountability, and which display the greatest sense of public responsibility. Acceptable systems must maintain standards of excellence without encouraging monopolistic practices. Private sector programs like AALA must earn acceptability by assuring accountability, which should be built into government programs. Government accreditation programs must overcome bureaucratic problems to achieve the efficiency and cost-effectiveness more readily attained by private sector programs. However, efficiency will be judged on the basis of equality of programs.

Swankin stated that NVLAP should not have an exclusive charter in the laboratory accreditation field, but also indicated that AALA and other private accreditation programs should not have status that they do not earn. The proposal that NVLAP serve to accredit laboratory accreditation programs could be a good idea for the future, when private sector programs demonstrate their quality, integrity, and accountability. Then one could compare accreditation programs in regard to service to small laboratories, investigatory processes, advertising policies, accountability, efficiency, adaptability to new technologies, and service to the public interest. Swankin suggested that a small, broadly representative group might be assembled to prepare a 5-year plan with measurable milestones. Its goal would be the evolution of NVLAP into an accreditor of accreditors.

DISCUSSION

One attendee wondered how very broad generic criteria, such as ASTM standard E548, can be used to properly support accreditation programs based either on product areas or disciplines. When are specific technical criteria needed for a valid accreditation program developed, and how are specific criteria developed for a program based upon broad disciplines? It was noted that work is underway by various ASTM committees for different product areas. AALA had asked ASTM Committee E36 to coordinate these splintered activities within individual discipline accreditation standards. Standards of criteria are needed that cover all the capabilities of the laboratory, whether it is a manufacturer's specialized product testing laboratory or a diversified independent laboratory. It was observed that accreditation criteria standards are generally very broad, such as ASTM E699 covering test methods developed by ASTM Committee E6 on buildings and structures.

CRITERIA FOR RECOGNIZING LABORATORY ACCREDITATION SYSTEMS

ASTM Committee E36 (page 68)

Gerald Berman's paper, "Work of ASTM Committee E36 on Criteria for Testing Laboratory Evaluation and Accreditation," noted the accomplishments and activities of this committee since it was established in 1973. To date, Committee E36 has developed and promulgated ASTM Standard E548, "Recommended Practice for Generic Criteria for Use in the Evaluation of Testing and Inspection Agencies." Widely referenced by many accreditation systems, E548 provides guidelines on information that laboratory evaluators and accreditors should seek regarding laboratory organization, human and physical resources, operational procedures, and quality assurance practices. At present, it does not specify minimum requirements for an organization to be assessed as competent.

Viewing a model of an accreditation system as consisting of an accrediting authority, accreditation criteria, and an evaluation and monitoring process, Berman noted that Committee E36 has embarked on the development of standard documents to serve these component elements.

A draft document has been prepared identifying the elements and attributes that should be present in a laboratory accreditation system. A similar document was presented at the International Laboratory Accreditation Conference (ILAC). The draft includes those attributes of a laboratory accreditation system:

- It should accredit testing laboratories on the basis of national or international standards for well-defined fields of testing, scientific disciplines or technologies, or in relation to specific products or tests.
- Its technical criteria for accreditation should be formulated by persons technically competent in the relevant field of testing.
- Its criteria should be published and readily available.
- Its assessors should be impartial experts in the testing area involved.
- Its assessments should include written reports.
- It should reassess accredited laboratories periodically.
- It should publish a list of accredited laboratories and the scope of accreditation, and should maintain a record of tests for which each laboratory is accredited.

Committee E36 is also reviewing a controversial draft of a standard covering generic criteria for use in evaluating and accrediting laboratories. The draft subsumes the information disclosure sections of E548 by adding sections of generic requirements to be met by the laboratory. The requirements are similar to those contained in proposed revisions of ISO Guide 25. Berman noted that adding generic requirements to the information disclosure sections of E548 may encourage harmonization of criteria and language used by existing accreditation systems. This will give impetus to mutual recognition among systems and reduce duplicative evaluations. Stressing that the requirements of this draft document are completely generic, Berman pointed out that specific benchmarks for determining compliance with generic requirements would be the province of the accreditor.

Alternatively, specific criteria for test methods could be established by technical committees with responsibility for the test methods, enhancing the potential for reciprocity among accrediting systems.

Berman mentioned that a new subcommittee has been formed to define areas of testing or disciplines in terms of test method groupings, procedures, or techniques.

A Certifier's View of Accreditation (page 70)

In his paper, "Characteristics of Laboratory Accreditation Systems—The Product Certification Program Point of View," Theodore Pritsker defined "accreditation as a systematic approach to universal acceptance by numerous parties." He excluded individual relationships between purchasers and suppliers. In regard to "laboratory accreditation," he suggested that it would be unwise to limit the extent of accreditation under consideration. He noted that there are several certification programs which might prefer to accredit the laboratories they wish to use, and that it might be appropriate to subject some design evaluators or evaluative agencies to accreditation. He considered four aspects of accreditation from the certifier's view—adequate testing, relationship with testing laboratories, product liability, and minimum requirements of an accreditation system.

Pritsker noted that the certifier needs laboratories that provide reliable results to serve as a basis for certification. He observed that some certification programs use multiple cooperating laboratories, others use inhouse laboratories at several locations. These certification programs require laboratories of proven ability that can produce results comparable from laboratory to laboratory. The certifier needs laboratories that are accredited by a system with resources to function properly.

Pritsker suggested that the relationship between certifier and testing laboratory should be minimized. Certifiers should accept results from properly accredited laboratories, advising the accreditor if discrepancies become apparent. Without accredited laboratories, certifiers must "accredit" them by contractional arrangements that specify conditions for acceptability, cancellation, limitations, and costs of maintenance. The relationship is "sticky" when the certifier is also the testing laboratory.

Regarding the issue of product liability, Pritsker indicated that several certifiers of safety-related items have been held liable, but is aware of no cases where laboratories or certifiers have been involved when only product performance is the issue. He asserted that contractural arrangements between parties and the claims of certifiers and manufacturers, rather than accreditation, are factors establishing responsibility in product liability actions. However, accreditation might enhance the credibility of certification agencies in the courtroom.

Pritsker discussed the minimum requirements of an accreditation system. Observing that the accreditee poses no problem in definition and that requirements for criteria and methodology can be found in standard references (e.g., ASTM and NVLAP), he asserted that the real question is, "Who is to be the accreditor and what are his minimum requirements?". As a certifier he wanted the accreditor of laboratories to have: technical expertise, competent personnel, ability to evaluate and transmit the current and the latest methodology, organizational/administrative ability, and unassailable and unquestionable integrity beyond reproach.

According to Pritsker, the costs of accreditation will play a minor part in a laboratory's budget if the accreditor meets the above requirements and is not trying to make a profit.

Pritsker characterized an accreditor as an evaluator and communicator rather than a police officer. Accreditors should inform their clients of the latest developments in technology and feed back problems and experiences to the standards writing agencies. Accreditors must be open-minded, self-evaluating, and sensitive to the impact of accreditation. There must be appeal mechanisms and the capability of ascertaining the propriety of denying or revoking accreditation. The accreditor's staff should be professional and motivated to provide excellence rather than the status quo. The relationship between accreditor and accreditee must be one of mutual respect and trust.

Pritsker asserted that integrity beyond reproach is the most important and absolutely essential requirement for any accreditor. The accreditor's only motive must be to upgrade the testing field for the benefit of clients and industry. There must be no other motives, such as financial concerns or putting all laboratories on an equal basis. The accreditor should not promote the benefits of specific laboratories or of any association. Pritsker asserted that no organization of laboratory members can become an accreditor because its base is inherently suspect.

Pritsker observed that if a basic requirement for an accreditor is integrity beyond reproach, then there is no need for an accreditor of accreditors. Integrity and reputation beyond reproach cannot be gained by an additional layer of accreditation. Integrity and reputation must be earned. Accreditation only evaluates performance, it cannot evaluate self interest, motivation or intent. Pritsker concluded that a Government agency, such as NBS, must perform the primary role in laboratory accreditation, unless ASTM or ANSI or a similar organization offers to fill the role.

The AALA Proposal for Recognizing Accreditation Systems (page 73)

In his paper, "General Guidelines for a Laboratory Accreditation System," John Magnotti recommended that the guidelines for the operation of laboratory accreditation systems, as developed by Task Force C of ILAC, be used by NVLAP to implement the proposed role of serving as an accreditor of accreditation systems. Claiming that the purpose of his paper is to summarize these ILAC guidelines, which have been endorsed by AALA's Board of Directors, Magnotti noted that these guidelines are consistent with the guidelines being considered by ASTM Committee E36. According to Magnotti, the guidelines recommend that a laboratory accreditation system have the following operational requirements:

- The system must be actively engaged in accreditation of testing laboratories.
- The system should accredit in terms of nationally or internationally recognized standards or other well-defined standards and test methods within well-defined fields, scientific disiplines, or technologies.
- Technical criteria should be published and generally available, and should be formulated by appropriate technical experts. Criteria should be consistent with the current proposed revision of ISO/ILAC Guide 25.
- Laboratories should be assessed by impartial experts rigorously selected in accordance with clearly defined criteria. Assessments should be supported by written reports.
- The system should include a broadly based, impartial body that reviews assessment reports and acts as the technical accrediting authority.
- The system must provide continuous accreditation by inspection, proficiency testing, and requirements for laboratory information updates. Physical assessment should be sufficiently frequent to ensure competence and credibility.
- Lists of laboratories should be published, including their general capabilities and the scope of their accreditation. The publication should include the general features of the accreditation system.
- The system's precise policy dealing with advertising by accredited laboratories should be published. The policy should specify the citation to be used with the system's logo or acceptable forms of laboratory advertising.
- The system should have fully documented procedures, including a contractual arrangement between the accrediting authority and accredited laboratories.

Magnotti concluded that a laboratory accreditation system must have complete and technically accurate documentation, impartial and competent assessors, and clear, understandable, and enforceable policies.

An attendee suggested that AALA was proposing a two-tiered bureaucracy with the inefficiency that this implied. Theodore Pritsker agreed, and noted that he knew of no other accreditation program looking to be accredited, in turn, by the Government. Magnotti responded that the AALA proposal did not have both NVLAP and the accreditors doing the same thing, but that the Government would serve as the arbiter of private sector accrediting systems and the necessary link to the international community. He observed that there is need for Government to provide some consistency among U.S. accreditation systems, as required by the international community. Gerald Berman noted that ASTM E36 Committee's intent is to develop standards that can serve as a basis for such uniformity.

An attendee asked as to what was being done to encourage harmonization, reciprocity, etc. with Canada, noting that Canada now has an accreditation system. Louis Rossi of AALA indicated that AALA had contacted the Canadian Standards Council, received information from them, and intended to pursue it further.

Another attendee stated that it is not necessary for Government to approve accreditation systems. Noting that there is an existing and tested operating structure in the United States with criteria applicable to several areas, she inquired whether AALA has a framework for accepting accreditations by other accreditors. AALA representatives responded that they proposed that NVLAP serve as the accreditor of accreditors.

Another attendee stated that laboratories vitally need a comprehensive national accreditation system to improve their own capabilities and to drive inadequate laboratories out of business. She noted that feuding between AALA and NVLAP should cease; neither system is adequate; some laboratories need accreditation by product, others need accreditation by discipline. It's time to cooperate in developing a comprehensive system that can do the job, she said.

The Certification Program of the International Electrotechnical Committee on Quality (IECQ) (page 74)

In the paper, "The IEC's Way of Evaluating Certifiers in Participating Countries," Howard Kontje describes the IECQ program as an international certification system for electronic components. The program is a system in which an international body, IEC, in effect accredits a national body. Manufacturers in each country may submit their products to an appointed National Supervisory Inspectorate (NSI). Each NSI evaluates the products in accordance with the appropriate component standard approved by the system, surveys the manufacturer's facilities, reviews the quality assurance program, and supervises qualification tests. It is anticipated that products granted a certificate of conformity will be accepted in other countries.

In conclusion, Kontje emphasized important elements of the IECQ product certification system:

- Laboratory capabilities are judged for specific product categories and in accordance with requirements for tests as specified by standards for those product categories.
- Laboratories are evaluated as part of the overall evaluation of manufacturers' quality assurance systems. For product certification, assessment of laboratories cannot be isolated from evaluation of the total quality assurance program.
- The surveillance program is ongoing, providing at least yearly site visits to factories and laboratories to verify continuing compliance with requirements of the system.

An attendee inquired about the IECQ fee structure for accrediting independent laboratories. Howard Kontje responded that the estimated cost for approving a laboratory for testing of a specific component (such as a capacitor) as covered by a sectional IEC specification was $3,000. He noted that this amount would not be multiplied by the numbers of different components tested. Economies would depend upon the relationship of components to the test equipment.

An attendee asked if UL , as the approved NSI for the United States, has to pass on to the IEC the criteria that are used to evaluate laboratories. What kind of consistency and detail in criteria from country to country is required by the IECQ acting as an accreditor of acceditors? Kontje replied that each country is responsible for determining the acceptance criteria for laboratories within that country, and that ISO Guide 25 is being used as the general guideline for such criteria.

Another attendee asked if Government funding of any sort was involved in the IECQ program. Kontje indicated that the program was a completely privately supported operation.

An attendee asked if the NSI is disqualified from doing the component testing required by the IECQ system. Kontje indicated that UL, as the NSI for the United States, will not perform the testing laboratory function. UL will conduct check tests to determine that laboratory output is correct. However, in many other countries in the IECQ system, the NSI is doing the testing of the component itself. The French NSI does all the testing of the components.

The International Laboratory Accreditation Conference (ILAC) (page 76)

Howard Forman commented on the objectives of ILAC and reported on the activity of one of its working groups in his paper, "ILAC: A Means for Removing Technical Barriers to Trade by Recognizing Laboratory Accreditation Systems in Different Countries." He stated that the objectives of ILAC are to promote development of national programs for accrediting testing laboratories, employing harmonized accreditation criteria, and then to promote the development of agreements by which importers accept testing by accredited laboratories in exporting countries. He asserted that an ultimate objective may be to promote worldwide agreement similar to the GATT code.

Observing that 42 countries and 12 international organizations have attended 1 or more of the 5 annual ILAC Conferences held to date, Forman noted that, in intervening months, various task and working groups have carried on relevant investigations as mandated by ILAC at its annual meetings. One working group presented its report to the ILAC 81 Conference in Mexico City, entitled, "Information on Bilateral or Other Agreements for the Recognition of Laboratory Accreditation Systems."

The report identified two bilateral agreements in actual operation. One agreement between Czechoslovakia and the German Democratic Republic provides for mutual acceptance of test data without reliance upon laboratory accreditation systems. The other identified agreement in operation, between the Testing Laboratory Registration Council of New Zealand (TELARC) and the National Testing Authority of Australia (NATA), provides reciprocal recognition of laboratory accreditation systems with the possible consequence of mutual acceptance of test data.

The ILAC Working Group also identified forms of recognition arrangements other than bilateral agreements. For instance, various foreign bodies accept test reports from laboratories accredited by the Danish National Testing Board. The countries of the European Free Trade Association (EFTA) have established a Convention for the Mutual Recognition of Inspections Regarding the Manufacture of Pharmaceutical Products. EFTA also has a scheme for recognition of pressure vessel testing done in the exporting country. The Working Group on Calibration Services, established by the Western European Metrology Club, announced in 1980 an agreement, "International Acceptance of Calibration and Measurement Certificates," and in 1981 published minimum requirements for mutual recognition of certificates. From its initial study, the ILAC working group concluded that reciprocal recognition of accreditation systems and mutual acceptance of test data across international boundaries are possible when national bodies or authorities are involved. The working group requested and received approval at the ILAC/81 annual meeting to continue its work and to develop guidelines that would serve as a basis for bilateral or other mutual agreements. The guidelines would include:

1. Prerequisites for an agreement
    - Description of accreditation system to be publicly available.
    - Scope of accreditation to be clearly stated.
    - National authority to be competent to enter into mutual agreements.
    - National authority to represent the scope of testing in agreements.
    - Systems' accreditation criteria to be those endorsed by ILAC.
2. Items to be covered by the agreement
    - A communication channel with an identified international contact point.
    - A channel for transmitting information on accredited laboratories and their fields of expertise.
    - Provision for requests between parties for additional information regarding tests and services of particular laboratories.
    - Provisions whereby experts could be interchanged for laboratory inspections.
    - Provisions for intercomparative testing.
3. Content and consequences of an agreement

    The agreement should specify binding consequences, such as a provision that one party will recognize the test results or the laboratory accreditation system of the other party as equivalent to its own test results or system.

An attendee, noting that the United States has many laboratory accreditation programs and that NVLAP has only three programs, asked whether the U.S. international position would be better served if NVLAP were to serve as the overall coordinator of U.S. laboratory accreditation programs. He questioned whether NVLAP and NBS could be the arbitrator of all U.S. programs and also accredit laboratories and compete with other national systems. Forman indicated that this workshop was to provide advice on this subject. Since the international aspect regarding laboratory accreditation was itself so new, Forman's opinion was that NVLAP should not change its direction.

The Organization for Economic Cooperation and Development (OECD) (page 79)

Carl Morris outlined several aspects of OECD's development of an international approach to mutual acceptance of test data, particularly in regard to chemical testing related to health and the environment.

The OECD expert group, under leadership of the United States, was established as a result of a 1978 OECD council decision giving high priority to development of principles of an international Good Laboratory Practice (GLP). The expert group was to provide for international discussion and agreement on such principles and also issues related to implementation of national GLP compliance within the international framework. Recommendations of the expert group would provide a basis for high-level OECD discussions.

Seventeen countries and the Commission of the European Communities participating in the OECD expert group developed the "OECD Principles of Good Laboratory Practice." The OECD council approved this document in May 1981 and recommended that it be provisionally implemented in member countries. Issues addressed in this document include: scope, purpose, and definitions; laboratory organization, facilities, equipment, and personnel; sample characterization, handling, storage, and disposal; reagents and solutions; standard operating procedures and study methodology; and procedures for health and safety, quality assurance, record retention, and waste disposal.

In May 1981, the OECD council also adopted a Decision Concerning the Mutual Acceptance of Data in the Assessment of Chemicals. This decision determined "... that data generated in the testing of chemicals in an OECD country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of man and the environment."

Noting that attainment of this goal could lead to elimination of duplicate testing and avoidance of non-tariff barriers to trade, Morris observed the need for countries to harmonize and implement the OECD test guidelines and principles of GLP, and to have in place an internationally harmonized national GLP program. In its second phase of activity, the expert group has addressed the issues involved in implementing the OECD principles of GLP at both the national and international levels.

At the national level, the expert group recommended that:

- National governments follow OECD principles of GLP,
- National governments have responsibility to implement a GLP compliance program,
- National programs provide laboratory inspections and audits,
- Inspections and audits be at sufficient frequency to assure continuing compliance,
- Qualified and properly trained inspectors and audit personnel be used.

At the international level, the expert group recommended:

- Establishment of national GLP compliance programs to assure application of OECD test guidelines and principles of GLP;
- Establishment of an international mechanism to recognize national GLP compliance programs;
- Development of a notification system whereby the OECD council can be advised that a member nation has in place the elements for mutual acceptance of data;
- Regular and complete communication among National authorities regarding compliance matters, including provisions for dealing with "questioned" data; and
- An International GLP Forum to share technical and administrative matters regarding GLP implementation.

Morris stated that the expert group has also developed "OECD Guidelines for National GLP Inspections and Study Audits" for use by national authorities and inspectors. The expert group has recommended that this document be accepted for use by member countries. In effect, OECD has developed an international system for mutually recognition of national laboratory accreditation systems.

An attendee asked whether EPA intends to use the OECD plan for the benefit of U.S. companies, and if so, when will EPA announce it. Noting that the U.S. has been an active participant in the OECD developments, Morris indicated that the U.S. position will be formulated only after the public comment period in early 1982. High level OECD meetings will occur in late 1982 and in early 1983 after which provisional implementation could begin. EPA is developing a proposal for health effects testing which is in fair harmony with FDA and OECD activity. The FDA and EPA compliance programs for health and environmental testing are being harmonized. An interagency agreement provides EPA with FDA inspections of laboratories for health effects tests. EPA assessors are inspecting environmental laboratories for compliance with good laboratory practice.

On the State-of-the-Art (page 81)

In his paper, "Recognition of Accrediting Agencies, State-of-the-Art," Theodore Young describes the program of the U.S. Department of Education (DOE) as representative of the state-of-the-art of an agency which accredits other accreditating agencies. He reviewed the history, scope, administrative structure, and procedures of the program, and identified a number of issues which could relate to laboratory accreditation.

Currently, the U.S. Secretary of Education is required by various statutes dating from 1952 to recognize and list accrediting agencies for postsecondary education. The program has procedures and criteria for recognition of private sector accrediting agencies, for recognition of State approval agencies for vocational education, and for recognition of State approval agencies for nursing education. Under these rules, some 80 private sector accrediting agencies and 20 State approval agencies are recognized. As a group, these recognized agencies accredit about 3000 universities, colleges, and postsecondary schools and about 8000 specialized programs of postsecondary education.

The process through which the program recognizes accrediting agencies has five stages. The applicant accrediting agency develops a petition consisting of a narrative statement with supporting documentation, showing compliance with the criteria. Next, the applicant submits the petition at least 3 months before a scheduled review by the Advisory Committee. The staff then prepares an analysis of the petition, visits the applicant agency, observes their administrative evaluation and accrediting activity, and interviews agency staff and other interested parties. An Advisory Committee conducts a transcribed public hearing, including the petitioning agency, the staff, and requesting third parties. Recommendations are forwarded to an Assistant Secretary for final decision. Recognition may be denied, deferred, or granted for a period up to 4 years. A statement of the scope of the agency's recognized accreditation activities is included. Listings of recognized agencies are published periodically in the *Federal Register* and appropriate brochures.

Criteria for recognition of accrediting agencies, first published in 1948, were revised in 1952, 1969, and in 1974. Six requirements in the 1948 criteria gradually increased to 47 requirements in the 1974 version. Whereas the 1948 criteria required an agency to provide on-site visits and published criteria and listings, the 1974 criteria require an agency to also have on-going evaluation programs, and self-analysis requirements for accredited schools involving faculty, students, staff, and other constituents. For recognition, agencies are now required to have published statements of key personnel, ownership, control, purpose, and objective; published standards and procedures for evaluation, accreditation, and appeal; and written guidelines and procedures for on-site examinations and handling of complaints.

Young noted one particular aspect of the program's criteria for recognition of accrediting agencies. The criteria, except for the 1948 version, are generally devoid of specific requirements that an accrediting agency needs to impose upon schools or educational programs; i.e., criteria for recognition of accrediting agencies do not embody criteria for the accreditation of schools. This is consistent with traditional Government policy that educational standards for postsecondary education are the province of the private sector and the States.

The record indicates that private sector accrediting agencies increased from 5 in 1928 to 78 in 1981, despite the introduction of increasingly complex criteria, and despite efforts by the program and national associations to control such proliferation. Young observed that rules and criteria of Education's National Recognition Program act to discourage duplication of accreditation activity but do not appear to discourage fragmentation of such activity. For instance, instead of a single recognized accrediting agency for the health technology field, there are 17.

Young identifies a number of issues and poses questions relative to a similar program in the testing laboratory:

- Whereas the DOE is the single Federal authority for education and depends wholly upon private and State accrediting agencies, and whereas accrediting agencies must be federally recognized if their members are to be deemed eligible for Federal funding, similar compelling associations are not apparent in the testing laboratory field for a centralized Federal recognition program or for accrediting agencies to seek such Federal recognition.
- Accrediting agencies for education are considered to provide a public service and, for recognition, are required to have a governmental or quasigovernmental character. Should a proposed recognition program in the testing laboratory field be restricted to accrediting agencies with a similar charter?
- Should criteria for recognition of laboratory accrediting agencies be limited to elements which assess technical and professional competence of laboratories, or should criteria also contain elements which assess public concerns such as accountability, integrity, due process, etc.? DOE's program criteria evolved from one to the other as its public profile grew.
- To what extent should fragmentation of the scope of laboratory accreditation be controlled? Can a recognition program for laboratory accrediting agencies place limits on the degree of specialization? Are there alternatives to an applicant accrediting agency defining the scope of accreditation?
- Education's National Recognition Program minimizes duplication of accrediting activities because it attracts all such accrediting activity to seek recognition under the program. What enticements could a program for laboratory accrediting agencies offer that would encourage such agencies to seek recognition and to submit to the program's requirements for coordination?

One attendee asked for references to the court case cited in the paper. The reference for the District Court decision is 302 F. Supp. 459 (1969); for the Court of Appeals decision, 432 F.2d650 (1970). The latter citation references the Supreme Court position.

Another attendee asked whether the effort and costs involved in DOE's National Recognition Program had improved the quality of life over its long history. Young observed that the program was first initiated to assist students in selecting schools, and educators in accepting transfers and graduate students. The program was later mandated by legislation, starting in 1952, to better assure that billion-dollar education subsidy programs were properly utilized. Quality of life was improved to the extent that students obtained more reliable guidance and protection from fraudulent educational programs.

Another attendee asked whether DOE's National Recognition Program pays for audits and inspections conducted by recognized accrediting agencies. Young indicated that DOE does not fund accreditation agency activities. Whether agencies pay their assessors probably differs from one group to another. The program's criteria require accrediting agencies to charge only reasonable fees for their accreditation services.

DISCUSSION

An attendee indicated that initially NVLAP could establish an accreditation program only if requested by an outside party, and only if the need was established. Only then could NVLAP establish standards and accreditation criteria and implement an accreditation program. Howard Forman confirmed that this is the general NVLAP procedure, 7a, except that the requestor, not NVLAP, has to identify exisiting standards to be used, as NVLAP does not develop standards, only the criteria by consensus procedures. The attendee asked if, under additional NVLAP procedures, any Government agency issuing standards could require NVLAP to establish an accreditation program to monitor such standards. Could that Government agency also establish the accreditation criteria without private sector participation? Under NVLAP, could a Government agency force affected parties in the private sector to participate in an accreditation program established by that agency?

An attendee noted that the answer is "yes," as this was done in establishing the NVLAP program for carpets. John Locke of NVLAP observed that the NVLAP Part 7b procedures, are for Federal agencies already having authority to determine need, to establish standards, and to determine compliance of products to the standards. Locke noted that the NVLAP procedures contain mechanisms for participation of the private sector. NVLAP publishes a request from the Federal agency in the Federal Register, providing for a 60-day comment period. Responses, with copies to NVLAP, are reviewed by the requesting Federal agency which must decide whether it has the right and authority to proceed with the requested accreditation program. With concurrence of the Federal agency that all public comments received have been addressed, NVLAP proceeds with the program. Howard Forman noted that in these NVLAP programs, NBS retains responsibility for laboratory on-site investigations and proficiency testing programs, and that DOC makes the final decision regarding a laboratory's accreditation. James Bryson of NBS added that any accreditation criteria proposed by the requesting Federal agency must be within the framework of the general criteria already established by NVLAP. A representative from the requesting agency for NVLAP's carpet program noted that criteria used in that program were already in Federal regulations 200.935 and are utilized in 14 existing HUD programs.

An attendee, noting the close relationship between standards development, laboratory accreditation, and product certification, asked if the public sector-private sector roles in standards and certification area could be models for similar roles in the laboratory accreditation field. Howard Forman stated his belief that standards development should essentially be a private sector activity and said he believed that laboratory accreditation has a different scenario. Voluntary standards have thousands of persons active in about 400 organizations with long histories of standards development. The 70 or so identified laboratory accreditation programs are generally specialized, and do not cover the overall needs for laboratory accreditation—the objective of the NVLAP and AALA programs. Thus, there would not be a case of Government getting out of something well established in the private sector. Forman indicated his support for the establishment of AALA, but noted that AALA had just started. Perhaps, in the future, when the private sector had established a track record, the question of Government involvement in laboratory accreditation should be reevaluated. The attendee agreed, with respect to present day circumstances, but still favored the principle of a joint Government/private sector effort, stating that NVLAP and AALA, operating independently, have less chance of survival. Earl Hess noted that Government officials frequently justify programs on the basis that the private sector is not capable of filling the need. He asserted that the private sector is ready to fill the need if the government will step aside.

Another attendee referring to the cost of funding the programs, indicated that it was important to compare costs, particularly the costs of examining the laboratories. He noted that the DOE program and the IECQ program for electronic components are self-supporting. Assessors for the Australian program are contributed by industry. We need to look at the implementation of the OECD activities by FDA, EPA, and other regulatory programs, he said.

A MECHANISM TO ACCREDIT ORGANIZATIONS WHICH ACCREDIT TESTING LABORATORIES

The AALA Proposal (page 92)

Louis Rossi, Chairman of AALA, noted in his paper, "Proposal, To Transfer the Current NVLAP System into a System for Accrediting Private Accreditation Systems," that the concern of this workshop was the future direction of laboratory accreditation and the recommendation that NVLAP assume the role of accreditor of accreditation systems and provide the link with the international laboratory community. Rossi pointed out legal and policy guidelines supported by the Reagan Administration as impetus for shifting laboratory accreditation to the private sector, noted the existence of criteria for standardizing and operating laboratory accreditation systems, and cited recommendations to be included in a proposed regulation to be published by DOC as a result of this workshop.

Regarding legal and policy guidelines of the current administration, Rossi referenced the recently published Office of Management and Budget (OMB) Circular A-119, stating that its general policy specifies that Federal Government will rely on voluntary standards for procurement; will participate in voluntary standards bodies when in the public interest and when compatible with agencies' missions; and will coordinate such participation to increase effectiveness and to ensure that Federal views are in the public interest. Rossi also noted the Reagan Administration's support of OMB Cirular A-76, which intends to enhance cost-efficient performance within the Federal Government by using the private market whenever possible.

Rossi claimed that laboratory accreditation programs can and should operate in the private sector. Transfer of the responsibility for accrediting laboratories to the private sector should begin now, with the Federal Government assuming a role as an accreditor of laboratory accreditation systems. This will relieve the current burden on the Federal budget. Beginning the transition process now will phaseout existing NVLAP programs as private sector accreditation systems respond and refine their accreditation capabilities. Rossi noted that a Federal precedent for programs to accredit accreditation programs has been long established in the DOE with its procedures and criteria for recognition of systems that accredit educational institutions. A program for accrediting systems that accredit laboratories is needed because manufacturers, consumers, and government need a basis for determining the competence and quality of the large number of existing laboratory accreditation programs. Since laboratories provide test data to support claims of conformity of products to standards, laboratory accrediting systems provide an essential service.

Using AALA as an example, Rossi claimed that the private sector is prepared to provide voluntary laboratory accreditation as NVLAP transforms its role to that of an accreditor of accreditation systems and primary U.S. link with the international laboratory accreditation community. AALA, patterned after Australia's national accreditation system, organizes its accreditation system by discipline. Laboratories are accredited for specific tests or groups of tests within disciplines or subdisciplines. This approach can provide laboratories with an evaluation for their total range of capabilities, and enables AALA to process a substantial number of accreditations in reasonable time.

Rossi observed that there are, in the private sector, independent, nonprofit organizations dedicated to voluntary laboratory accreditation which can maintain objectivity and balance in accreditation systems. In addition, many other systems exist for the basic purpose of certifying products and, in the process, accredit laboratories which test these products. Serious tasks facing private sector laboratory accreditation systems are providing for balanced representation of government and private sector interests, effectively disseminating fair and complete information, controlling advertising, and maintaining technically valid and well-accepted reaccreditation systems.

Rossi noted that the private sector cannot at this time provide a model for an overall laboratory accreditation system. It is not certain how the voluntary laboratory accreditation system will evolve as a cooperative venture with Government. He claimed that there will be a maturing and possibly a consolidation where one or a few systems will emerge as coordinating bodies for private sector laboratory accreditation effort. Rossi claimed that there is certain need for a body in the United States to accredit accreditation systems and to serve as the link between accreditation systems in the United States and other countries, presumably within the ILAC structure.

Regarding criteria for standardizing and operating laboratory accreditation systems, Rossi pointed out that if the Government accepts the proposition of accrediting laboratory accreditation systems, the evaluation criteria for accrediting such systems will be of paramount importance. Noting that ILAC criteria seem to require additional work and coordination, he suggested that these criteria, endorsed by ILAC 81, be used as tentative criteria subject to modification by ILAC or by the Government acting as an accreditor of accreditation systems. Rossi observed that use of these criteria would provide a solid base for an eventual interlocking network of global accreditation systems. He also noted that ASTM Committee E-36 is developing similar criteria through the consensus process.

Rossi reiterated highlights of these ILAC criteria:

- Accreditation systems must specify their accreditation in terms of nationally or internationally recognized standards and test methods in relation to well-defined fields of testing, scientific disciplines or technologies, or specific products or tests;
- Accreditation criteria must be published and generally available;
- Evaluation of technical competence of laboratories must be in terms of ISO/ILAC criteria consistent with ISO Guide 25;
- Accreditation systems must provide for periodic reassessments of accredited laboratories and written assessor reports; and
- An impartial and independent appeals procedure must be available to resolve disputes associated with accreditation.

Rossi concluded by recommending that the role of NVLAP be transformed to one of accrediting accreditation systems and providing that critical link with the international laboratory community, to be accomplished as follows:

1. NVLAP would establish no new laboratory accreditation programs.
2. During the transition, private sector accreditation systems would accept the NVLAP accredited laboratories until accreditation expires.
3. Documents concerning specific areas of the accreditation procedures, including applications, checklists, advertising policy, and assessor qualifications would be reviewed and rewritten as necessary.
4. The adoption, at least in draft form, of the work done by Task Force C, Working Group One of ILAC, in creating criteria would be used in evaluating laboratory accreditation systems.

DISCUSSION

Opening the workshop to questions and opinions from the floor, the session moderator, Stanley Warshaw, noted that AALA's proposal included more than transferring an existing Government activity to the private sector. The proposal includes the establishment of a new Government effort: the accreditation of private sector accrediting bodies. The discussion that followed not only responded to the AALA proposal, but also concerned the need for laboratory accreditation, and the significance of discipline versus product accreditation, and included questions about AALA and NVLAP.

Response to the AALA Proposal

Noting that the AALA proposal admitted uncertainty with regard to the model to follow in switching Government responsibility for laboratory accreditation to the private sector, one attendee suggested that the collaborative effort between the National Institute for Occupational Safety and Health (NIOSH) and the American Industrial Hygiene Association (AIHA) could be an example. He stated that the AIHA accreditation program for industrial hygiene laboratories was initially assisted by Government funding, particularly for a proficiency testing program, and is now totally self-sustaining. NIOSH is no longer technically involved.

Howard Forman noted that NVLAP intended to become self-sustaining, so that one of the benefits claimed for the AALA proposal—to save money for the Government—is not a strong point. Forman asked if there might be other reasons in the public interest why the change should be made, such as more efficient, meaningful, or effective accreditation. Rossi responded that AALA's proposal was based upon the current situation and not upon possible future conditions. At the time of the workshop, NVLAP was not self-sustaining. Warshaw observed that the AALA proposal's intent was to follow current Administration policy; namely, to transfer Government activity to the private sector when the private sector is able to conduct such activity.

Another attendee asked why an organization such as his, currently accredited by and satisfied with the NVLAP system, should have interest in the AALA proposal. What is the benefit of AALA over NVLAP accreditation? Rossi indicated that AALA did not propose to be the only accreditation system, or to provide better benefits to the accreditee. The AALA proposal was that any accreditation system should be under an umbrella such as that to be provided by NVLAP. The attendee asked how AALA's proposed accreditation process would differ in operation from the current NVLAP process. To clarify the question Warshaw asked, if AALA picked up the NVLAP activity, would laboratories be accredited for product testing or on a discipline basis? Rossi stated that, following a transition period, laboratories would be accredited on the basis of discipline standards.

Noting that although AALA apparently believes that concurrent and independent operation with NVLAP is unsatisfactory and that the AALA proposal allows for concurrent operation of more than one accreditation system, Howard Forman asked how the AALA proposal would help AALA or the public interest. Rossi indicated that he couldn't answer this question, as he didn't know how private sector accreditation systems would evolve under AALA's proposal. Warshaw stressed that the AALA proposal would allow practically any accreditation system that wished to be accredited by the Government to be recognized.

Another attendee observed that if the Federal Government accredits accreditors and the accreditors do the work the Federal Government is now doing, it would seem that increased, rather than reduced, costs would result. Rossi expressed the opinion that NVLAP accreditation on a product basis is too costly and time consuming. He said that AALA believes that many of the same objectives can be accomplished by accrediting on the basis of discipline standards.

Gerald Berman of NBS noted that, under the AALA proposal, AALA could potentially have one patron and NVLAP one client—not a very efficient or effective use of Federal funds. He asked whether AALA had identified other accrediting systems that would like accreditation by NVLAP. Rossi indicated that a purpose of this workshop was to answer this question. No other accrediting systems were identified.

An attendee stated that it is important in evaluating an accreditation system to assess the management function. He noted that NBS is a recognized authority for measurement in technological areas. The AALA proposal provided that NVLAP, under NBS, would become an assessor of accreditation management rather than an assessor of technological activity. He suggested that whether Congress would fund such NBS activity would require review by appropriate parties.

Earl Hess reiterated the point made in his paper—that multidiscipline testing laboratories and their customers need comprehensive laboratory accreditation programs, a need that has not been served by Government, specifically NVLAP's product-oriented laboratory accreditation programs. Because this need had been unmet for 10 years, multidiscipline laboratories had supported and developed AALA's discipline-oriented approach, putting their reliance in the private sector. If this was not the right answer, he asked, what were the multidiscipline laboratories and the users to do—wait for development of accreditation programs that serve this need, under NVLAP's new procedures under Part 7c, or the initiation and development of some new program? It would take Government too long to accomplish this, he said. Warshaw responded that the significant difference between the Government and private sector approach is the due process checks and balances built into Government actions. He noted that the proceedings of this workshop would be published in February 1982. Suggested alternatives contained in the proceedings wouuld need to be published for comment in the Federal Register—another 30- to 60-day period. If serious objectives did not arise, it would likely be next fall before alteration of the current NVLAP could occur. On the other hand, the referenced NVLAP procedures, Part 7c, were in effect and could be implemented immediately to establish needed programs. Hess observed that this response was the best reason given for switching to the private sector, where things can happen expeditiously. Warshaw noted that some others believe that private sector expediency is sometimes achieved at the expense of needed visibility, public scrutiny, and auditing.

Another attendee stated that accreditation by the Government rather than the private sector could reduce some of the duplication of accreditation programs, and would be more readily accepted by foreign governments.

The Need for Laboratory Accreditation

One attendee noted that the AALA proposal mentioned a strong demand for third-party accreditation. He asked for an identification of this demand from other than commercial laboratories. Another attendee wanted to know what body of facts substantiated the need for a centralized accreditation system. Louis Rossi responded that the AALA proposal referenced needs in the international area, mentioning ILAC's attempt to identify national laboratory accreditation programs. He also mentioned the interest in a national accreditation system as expressed at this workshop by the National Conference of States on Building Codes and Standards and by the National Institute of Building Sciences. Warshaw observed that market data was not available to demonstrate the need for third-party accreditation, but if there was no need there would be no customer demand in this free enterprise system. Another attendee stated that this workshop, concerning third-party accreditation, should disclaim any intent to sell a need for accreditation. Warshaw noted that the workshop was in response to requests from the private sector, and was not selling anything. Another attendee claimed that thousands of people in the coal industry demand and need third-party accreditation. A different attendee indicated that his company had been anticipating a national accreditation system for laboratories, particularly in environmental monitoring. He noted that they had initiated a voluntary good laboratory practices program, and now were establishing an internal accreditation program.

An attendee indicated that part of the record regarding need for laboratory accreditation had not been given at this workshop. He referred to the hearings held in the 1970s, including the OSHA hearings on laboratory accreditation. A major reason for these hearings derived from the practices of States, municipalities, and OSHA to require listing or labeling of products (certification) by nationally recognized laboratories. There is still need for a system to recognize such laboratories. This subject was also discussed in the FTC hearings relating to standards and certification. He noted that AALA, under a small contract with OSHA, developed a system and criteria for accrediting laboratories that certify occupational use products. He observed that this system plan has yet to be implemented by OSHA, but is being encouraged by a number of States. (See OSHA letter in Part 5 of these proceedings.) John Locke of DOC mentioned a related need. He noted that there is an ANSI program for accrediting certification organizations, but this was not the only need. Many laboratories wanted to be recognized for the testing of products rather than for providing quality control and other assurance requirements of a certification system. The need of these laboratories was served by laboratory accreditation systems. Ted Pritsker did not agree, claiming that laboratories serving certification programs are normally approved by the certification program. An attendee did see a difference between accrediting laboratories and accrediting certification programs. For instance, OSHA would use AALA to accredit laboratories serving certification programs, where OSHA would retain responsibility for assuring that the functions of the certifying body are adequate. In regard to ANSI's accreditation of certification programs, he noted that there had been little demand for the service to date.

Howard Forman suggested that a market survey be conducted to determine who really wants laboratory accreditation, other than those who have mandated such requirements in regulations or in contracts. Then the type of accreditation system that would best serve the need could be determined. An attendee suggested that such needs be determined before any more accreditation programs are started. He noted that his laboratory is accredited by NVLAP because the Government requires accreditation for thermal insulation tests. His laboratory had the choice of using NVLAP or hiring outside services of accredited laboratories. But another attendee disagreed, believing that manufacturers and the testing industry created the need. He noted that as an engineer he couldn't obtain reliable engineering information. Someone pointed out that the aircraft industry required laboratory accreditation in the early 1960s. Because of conflict-of-interest concerns, ACIL rejected the idea of becoming a laboratory accreditation organization, and thereafter sought Government assistance. Someone else pointed out that voluntary laboratory accreditation was for those industries that need it. If you didn't need it, you didn't have to use it. A person noted the propensity for voluntary systems to become de facto mandatory systems, particularly in international trade.

Significance of Product Versus Discipline Accreditation

Two attendees pointed out that the AALA proposal included one issue that needs attention: the product versus discipline approach to accreditation. Rossi responded that although accreditation by discipline encompasses much more than accreditation by product area, both approaches were alike in some respects. Both approaches examined performance of specific test methods or groups of test methods. He suggested that the latest NVLAP proposal for a program in acoustical testing was really a discipline oriented laboratory accreditation program.

Gerald Berman of NBS stated that the difference between the product and discipline approach to accreditation was primarily a matter of semantics. He noted that the referenced NVLAP program in accoustical testing included some 50 test methods which, taken together, might constitute an acoustic testing discipline. Peter Forrest of the National Testing Laboratory Accreditation Service (NATLAS) of England agreed with Berman. He observed that NATLAS, NATA of Australia, and NVLAP of the United States all accredit laboratories to carry out particular tests or types of tests. Another observer indicated that if one were to evaluate a concrete testing laboratory on the basis of ASTM standard E329, using the discipline-oriented procedures of the Australian NATA program, one would have to evaluate the laboratory for 30 to 40 disciplines or subdisciplines.

Questions Concerning NVLAP or AALA

Louis Rossi indicated in response to a question that AALA was a nonprofit organization, as recognized by the Internal Revenue Service, sustained by membership dues, contributions, and accreditation fees.

Ted Pritsker expressed the opinion that the AALA proposal, in essence, requested the replacement of NVLAP accreditation activity by AALA. He said the workshop should have been provided background information on AALA: its financial capability, its inspection procedures, its appeal mechanisms, and its organizational structure. Warshaw, moderator of the session, asked if AALA would provide a background briefing to the workshop. Pritsker indicated that such a briefing at the end of the workshop would only contribute to the public record of the workshop, but would not provide attendees an opportunity to think about it or to question it. Rossi of AALA observed that the planning meeting, which was attended by Pritsker, had not scheduled a presentation of an AALA background paper, and therefore AALA was not prepared to provide such a briefing. Rossi noted that the workshop was assembled to consider a proposal made by AALA—not to learn about the AALA program. Warshaw observed that planning may have been inadequate regarding the need for briefings on AALA and NVLAP, but this should not hamper discussions of the main issue—whether the Government should alter its role in accreditation, and if so, how?

An attendee requested that two-page explanations of AALA and NVLAP be included in the workshop proceedings, with a matrix matching up the key elements of both programs. He suggested that a task group of AALA and NVLAP representatives be assembled to prepare these documents. Rossi requested that a recent ASTM article on AALA be included as an addendum to the proceedings. Warshaw indicated that these requests would be considered, subject to concerns regarding the cost and size of the proceedings. He noted that the NVLAP program was described in the Federal Register and in condensed summaries available at the workshop's registration desk. He also referenced the ASTM article describing AALA in a paper authored by Roger Amorosi appearing in *ASTM Standardization News*, Volume 8, Number 11, November 1980.

Another attendee expressed concern, but was unfamiliar with the mechanisms of the NVLAP and AALA programs. He noted that NVLAP's listing of accredited laboratories includes the laboratories of many suppliers. He interpreted this to mean that such suppliers were now accredited by the Federal Government to certify their own products. Warshaw said that such interpretation was wrong. He noted that accreditation was concerned with a laboratory's having capability to conduct certain tests and procedures. Accreditation did not concern itself with requirements for product certification, such as continued quality control. The attendee observed, however, that in laboratory accreditation the laboratory's equipment and personnel are certified. A laboratory was accredited to perform specific tests. If the laboratory performed such tests, the laboratory user must assume that they were certified tests. James Bryson of NBS commented that NVLAP did not certify people or equipment. He said that NVLAP determined that laboratory personnel were capable of performing a test in accordance with the standard, and that equipment was of the correct type and properly calibrated. Warshaw noted that ISO definitions distinguish between laboratory accreditation and product certification, as pointed out by Baron Whitaker's presentation. Laboratory accreditation could be considered as an incremental step in product certification.

FORMAL STATEMENTS PRESENTED BY ATTENDEES

Six formal statements were presented during discussion periods of the workshop. These statements are presented in their entirety in Part 4 of these proceedings. A summary of these statements follows:

A Statement on Laboratory Accreditation by the National Institute of Building Science (NIBS) by Joseph O'Grady

The subject of certification and related topics pertaining to building products, materials, subsystems, and systems is one of the highest priority issues in the NIBS 1982 Program Plan. The subject of laboratory accreditation and this workshop is of interest and concern because the purpose of laboratory accreditation is to maintain an acceptable level of quality in laboratories, providing reliable test results upon which to base such efforts as product certification. NIBS is in favor of laboratory accreditation to be provided by a recognized nationwide system that would tend to eliminate the need for duplicate accreditations. Although not yet in agreement on the form and management of such a nationwide system, NIBS will continue to serve as a forum where all sectors of the building community can address the issue.

Contribution to the Discussion by Peter Forrest

The United Kingdom's recently established National Testing Laboratory Accreditation Scheme (NATLAS) is Government-based under the auspices of the Department of Industry. It is Britain's counterpart to NVLAP. In developing NATLAS, an appointed steering committee, representative of testing laboratories, their customers, and accrediting organizations, considered whether NATLAS should accredit existing systems or seek to incorporate existing systems into one central system that would accredit laboratories in accordance with a single set of regulations, accreditation standards, and criteria. The latter option was chosen because:

- Direct accreditation by the Government NATLAS would be more readily recognized and accepted by laboratories' customers;
- Participation of existing systems in NATLAS, rather than their operating independently, would reduce the duplication and multiple assessments of laboratories; and
- Negotiations for mutual recognition between a centrally controlled and operated NATLAS and other nations' laboratory accreditation systems would be eased; also, better overseas acceptance of tests results furnished by laboratories accredited directly by NATLAS.

Forrest noted that of eight existing laboratory accreditation programs identified in the United Kingdom, five had already agreed to participate in NATLAS. The five agreed to recognize NATLAS accredited laboratories, to encourage their accredited laboratories to join NATLAS, to discontinue, where practical, independent assessments of laboratories, and to provide for assessors to operate on behalf of NATLAS.

Position Statement by W. D. Edsall

Representing the Committee on General Metallurgy of the American Iron and Steel Institute (AISI), " . . . the senior technical committee for the steel industry . . .", Edsall identified at least three interest groups at this workshop: NVLAP, representing NBS interests; AALA, representing the interests of the American Council of Independent Laboratories (ACIL); and the interests of major manufacturers operating captive laboratories. He observed that the steel industry operated about 700 laboratories, and speculated that the petroleum industry operated about the same number. He noted that these industries sold all of their products to specifications, and their laboratories were under continuous audit and survey by their customers. Edsall claimed that neither he nor the technical people of AISI were convinced that there was a need for third-party laboratory accreditation. He asked, where was the absolute proof that captive laboratories of manufacturers needed third-party accreditation?

If independent commercial laboratories such as those in ACIL need a laboratory accreditation program, they should decide as to what best suits them and their business environment. If or when a need for accreditation is proven for captive laboratories, it is unlikely that AALA would be accepted as a meaningful third party. Such accreditation must carry the stamp of the U.S. Government to be meaningful in the world's markets, Edsall said.

In this event the U.S. Government should not actually do the accreditation, since it lacked, he said, sufficient qualified people to survey and audit all the laboratories. The Government should instead define evaluation and accreditation criteria similar to those in 10 CFR 50. The Government should then recognize organizations to do the evaluations and accreditations, providing audits of the recognized programs. Accreditation certificates issued to laboratories should carry a U.S. Government imprint, Edsall advised.

Comments on the AALA Proposal Pertaining to Laboratory Accreditation by Derek Barton

Laboratories need to establish acceptance in the marketplace based upon their performance rather than their accreditation. However, Underwriters Laboratories (UL) does not oppose laboratory accreditation in principle, provided it is based upon valid specific criteria and provides reasonable assurance of compliance. In general, UL considers NVLAP an effective response to identified needs in specific product areas.

NVLAP's effectiveness can be endangered if laboratory accreditaton is considered synonymous with, rather than an element of, product certification. Its effectiveness can also be damaged if requirements for participation are diluted in an attempt to attract broader interests and participation. Valid laboratory accreditation requires identification of specific products and test methods, tailoring accreditation criteria accordingly. UL believes that NVLAP should continue accreditation programs in specific areas where need is determined to exist.

UL opposes the proposal that NVLAP accredit laboratory accreditation systems. Many special-purpose laboratory accreditation programs in the public and private sector have operated successfully without higher levels of supervision. Addition of this unnecessary function would impose further costs upon consumers and provide credibility to accreditation programs (and their accredited laboratories) that would be unjustified because, of necessity, only broad criteria and low levels of supervision could be provided. The Department of Education's programs for recognition of educational accrediting agencies, suggested by the proposal as a model, were mandated by law as a condition for granting Federal funds. UL believes that for privately operated businesses, such as those in the field of laboratory accreditation, such regulation is unnecessary.

Position Statement by Robert Woodall

NVLAP should retain its present role, but the program should be modified to provide expanded benefits at reduced cost. Dealing with unmanageable numbers of specific test standards, whether product or discipline oriented, should be abandoned in favor of assessing generic concepts of good laboratory practice and qualifying laboratories' basic quality assurance systems. Paperwork must be relieved. Efforts in this direction, supported by NBS's adequate provision of specific proficiency test samples, would discharge DOC's responsibilities, both domestically and internationally. DOC should neither substitute for nor expand into the area of accrediting accreditors. Specific accreditation programs should be left to the judgement of our free enterprise system.

An Opinion on Laboratory Accreditation Policy

by Geoscience, Ltd.

There are disadvantages in accrediting laboratories by complete field rather than by specific tests. One, the quality of the performance of specific tests could be lowered. Two, the services of small but high-quality laboratories that serve only one or two test methods could be lost. It is better to accredit by test method than by entire field.

There are important advantages for Government, such as NVLAP, acting as the accrediting agency for testing laboratories:

- NBS has a high level of technical and scientific achievement that can be brought to bear on the accreditation procedure.
- The Government can be impartial, effectively balancing competitive forces that exist in regard to test methods, procedures, and accuracy requirements.
- The prestige of Government plays an important role in international acceptance of U.S. laboratory accreditation.

WRAPUP

Dr. Stanley Warshaw, NBS program manager for NVLAP, closed the meeting by giving his tentative views of the workshop's discussions. He noted a lack of consensus on the issues and observed that the comments, criticisms, and suggestions were not too different from the record of the past.

Warshaw claimed that, based upon the input at the workshop, he would have a difficult time in today's economic climate to justify NVLAP's current program or any Government role in the laboratory accreditation area. The proposal that NVLAP become an accreditor of laboratory accreditation programs he viewed as academic at this time as the need for accreditation expressed at this workshop seemed to be conjecture.

Observing that market demand evidences the need, Warshaw noted that NVLAP had three current programs and two more ready to go. He observed, however, that there was some Government self-feeding in these programs. On the other hand, he observed that AALA had only accredited seven laboratories, six of which are members of an organization (ACIL) that represented about 5 percent of independent laboratories.

Warshaw questioned whether a Government role in laboratory accreditation was necessary to assure international recognition, citing the IECQ program as an example of a private sector approach. The degree of success of this program after its January 1982 initiation may provide evidence of the need for Government involvement in international activities. He referred to the Workshop paper by Don Abelson of the U.S. Trade Representative's Office, which said that the United States takes the view in negotiations with other countries that we do things within industry in America; that we utilize self certification and do not have government test laboratories involved in everything.

Warshaw stressed that these opinions were his personal assessment of the information so far received. He urged those having different perceptions to communicate their opinions within 30 days of the workshop so that they could be included in the analysis of comments.

Part 2

SUMMARY OF POST WORKSHOP COMMENTS

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INTRODUCTION

Part 2 of the workshop proceedings summarizes the first 43 letters received in response to DOC-NBS requests for comment concerning the major issues considered by the workshop. The request for comments was published in the *Federal Register* (FR), August 12, 1981. Thereafter, a copy of this FR notice was distributed by letter to NVLAP's general mailing list of persons interested in or concerned about laboratory accreditation. In addition, the attendees at the Workshop were orally invited to submit their written comments. Finally, a letter reminding interested persons to submit comments was distributed by NVLAP on November 30, 1981.

In this summary, numbers in parentheses refer to the number designation given to the letters of comment as listed in Part 5 of the proceedings' Table of Contents. The reader who seeks more information concerning the position, comments, or opinion summarized in this Part may refer to the letter referenced by this number designation.

Issue Number One

"Whether the DOC should abandon its present role and substitute in its place a program to accredit organizations which, in turn, would accredit private sector testing laboratories." Forty-two letters addressed this issue in some manner.

Seven letters, or about 17 percent of the responses, favored DOC-NBS abandoning its role as a direct accreditor of testing laboratories while retaining some role as an accreditor, coordinator, or monitor of laboratory accrediting organizations. Only three of these letters (8,9,12) specifically supported the AALA-ACIL joint proposal. All of these responses were from independent commercial testing labortories, one of which is currently accredited under NVLAP's thermal insulation program; another laboratory is evaluated for concrete testing (not accredited) by the ASTM-NBS CCRL program. According to these laboratories, Government interference in private business has been devastating (8); the NVLAP program is too limited and costly (12); and NVLAP is unworkable and unrealistic (9). The other four letters of this group (4,11,13,43) suggest arrangements that are essentially alternatives to the AALA-ACIL proposal. One of these responses (4), representing State highway and transportation officials, opposes the AALA-ACIL proposal on the basis that it would encourage unnecessary proliferation of accrediting agencies. They prefer a system that would utilize existing laboratory evaluation programs to their maximum effectiveness. Responses from a practicing consultant (11), a university laboratory (13), and a manufacturer (43) favor accreditation of laboratories by others, with DOC performing a coordination, guidance, and surveillance function.

Twenty-six letters, about 62 percent of the responses, supported the continuation of the NVLAP program. These letters were submitted by a technical society (23); a university professor (25); consultants (2,26); trade associations (16,19,32); manufacturers (18,28,35,36,38,39,40,42); testing laboratories, including inhouse laboratories (1,3,7,17,22,34,37); and independent laboratories (5,15,27,30). The testing laboratories are all accredited under NVLAP programs. Advantages of the NVLAP system frequently addressed by these letters include the following:

- NVLAP is achieving the credibility needed for acceptance at the sub-national, national, and international level (2,7,16,22,25,27,28,30,32,34,35,37,42). At this time, the participation of the Federal Government is necessary for such credibility and acceptance (2,7,16,22,23,25, 27,28,34,35). The association, participation and technical support of NBS is particularly important (5,7,16, 19,25,30,34,35).
- NVLAP provides opportunity for consolidation of needs for laboratory accreditation, thereby lessening trends toward proliferation of laboratory accreditation programs and duplication of effort (1,2,7,15,16,19,27, 28,30,34). NVLAP needs greater promotion and/or broader scope (1,15,19,27,28,34,39).
- NVLAP should provide laboratory accreditation programs to serve only proven needs (2,18,26,27), in response to public input (2,7,16,35), and in a voluntary and consensus mode (2,7,16,18,27).
- NVLAP programs provide a worthwhile professional standard (1,3,5,22,23,26,27,30,35,36,37,38,39,40) and improved quality assurance (1,3,5,22,23,36,37,40).
- NVLAP is achieving cost effectiveness (5,7,16,26) and is potentially self-supporting (2,7,16,19,23,42).

Nine letters, or 21 percent of the responses are either uncertain about or opposed to NVLAP's serving as an accreditor of laboratories or as an accreditor of laboratory accrediting agencies. These letters were received from manufacturers (14,20,21); an independent laboratory (10); a technical society (6); a trade association (24); an association of building code officials (29); a Federal agency (31); and an individual (33). The positions of these respondents are:

- In general, laboratory accreditation should be a private sector function and there is no need for a Federal accreditor of laboratory accrediting agencies (6,10,20,21,29).
- Self-evaluation or self-accreditation by laboratories to appropriate voluntary standards should be promoted (14,24).
- Need for additional laboratory accreditation or the manner of its implementation requires further study (31,33).

Issue Number Two

"What, if any, additional measures should be taken to assure that an effective U.S. presence remains in international laboratory accreditation activities, including bilateral arrangements?" Ten letters responded to this issue.

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*Prepared under contract.

Three responses specifically supported continued DOC participation in the International Laboratory Accreditation Conference (ILAC) (2,18,28).

- An NBS workshop on international laboratory accreditation is proposed to consider topics such as: determining U.S. input to ILAC, and the future role of ILAC in international trade (2).
- An advisory group representing major industrial associations should be appointed to advise U.S. delegates to ILAC regarding industrial interests (18).

Seven responses suggest other approaches to international laboratory accreditation (12,14,15,19,20,26,29).

- The private sector should seek involvement in international laboratory accreditation when it is economically attractive (20) or of interest to the voluntary standards system (26). Government involvement should be limited to intergovernmental actions (20).
- The American National Standards Institute and DOC should collaborate to promote mutual acceptance of the various mandatory and voluntary approaches of participating countries (14).
- DOC should retain an international involvement regarding laboratory accreditation (12) while seeking a mechanism for mutual approval of test results (29).
- Reciprocal agreements should be arranged with foreign countries providing for acceptance of test results rendered by NVLAP accredited laboratories (15).
- NVLAP should be publicized as an NBS program, to better enhance NVLAP's worldwide acceptance (19).

Issue Number Three

"What action, if any, can be taken by the private sector and/or the Government to reduce the proliferation of inspections and paperwork arising from duplicative accreditation activities within the United States?" Twenty-one letters responded to this issue.

Fifteen responses indicated a belief that there is need for a central accreditation system (1,2,4,7,10,15,16,19,21,25, 27,28,29,30,34). All but three (10,21,29) of these letters specifically identify NVLAP as being the appropriate agency. Some suggestions for NVLAP's improvement are:

- NVLAP should seek reciprocity with credible existing programs (4,19).
- NVLAP should accept responsibility for recognizing credible existing programs upon request (19).
- NVLAP should encourage Federal, State, and local interests to utilize NVLAP (15,19,27).
- NVLAP's accreditation of a test method under one accreditation program should be recognized under other NVLAP programs (15,19).
- NVLAP should reduce the amount of paperwork required (1,34).
- National building code groups and organizations listing laboratories should be urged to utilize NVLAP (15).

One letter suggested a voluntary coordination between existing private sector efforts (29). One response (21) calls for an organization to develop unified product certification approaches for States and building code groups.

One letter proposed some methodology to identify, evaluate, and improve existing systems before creating additional ones (33).

One letter suggested limiting accreditation efforts to programs conducted by professional societies (13).

One letter saw no need for reducing duplicative efforts (20).

Three letters expressed a belief that duplication of efforts could be reduced by relying upon the voluntary consensus system (14,18,26).

- Inspections and accreditation efforts could be reduced by laboratories' compliance with voluntary standards developed for the purpose of self-accreditation (14).
- Peer groups should implement evaluation and accreditation criteria standards developed by voluntary consensus groups. An optional central agency should approve and audit such implementation upon request (18).
- Federal, State, and local agencies should be encouraged to use and rely upon the U.S. voluntary standards system (26).

Opinions and Comment on Other Subjects

Two letters commented on the costs of NVLAP accreditations (19,27). One response (27) proposed that reduction of cost should be a priority effort. One response (19) suggested the appointment of an advisory committee consisting of one representative from each NVLAP accreditation program. Such a committee would recommend ways of improving effectiveness and reducing costs.

Seven letters commented on the issue of accrediting on a product-by-product basis versus accrediting on a discipline basis (2,5,7,9,12,16,19). Two responses noted that accreditation by product derives from NVLAP's receipt of public comments during establishment of the program (7,16). Two responses (5,19) said that accreditation by product best served the needs of their laboratories. One letter (9) claimed that accreditation by discipline is required for any laboratory accreditation system. One response (12) advised that accreditation by discipline would be more suitable for the writer's own laboratory. One letter (19) suggested that accreditation by product and accreditation by discipline are probably both necessary. One comment (2) advised that NVLAP procedures allow for both types of accreditation program.

Two letters commented on justification of needs for laboratory accreditation programs (26,27). One letter (27) advised that NVLAP should not seek to accredit accreditors or to replace other adequate laboratory accreditation programs—this places too much authority with NVLAP. Furthermore, NVLAP should guard against establishing accreditation programs with the sole purpose of changing market acceptance of particular types of laboratories. Another letter (26) suggested that NVLAP should establish a periodic review of continuing needs for its ongoing accreditation programs.

One letter (26) questioned whether DOC and NBS have the capability or the authority to become an accreditor of accrediting agencies. It was pointed out that this function would involve the review of the management of accrediting agencies rather than the review of technical competence of testing laboratories.

One letter (31) advised that there is no existing plan to utilize criteria developed by AALA in implementation of an OSHA program for laboratory accreditation. The applicable OSHA regulations (29 CFR 1907), are to be reviewed in accordance with the Regulatory Flexibility Act of January 1981.

One letter (41) dated December 29, 1981, advises that 20 laboratories have "committed" to membership and 32 laboratories have "committed" to accreditation under AALA procedures.

Part 3

FORMAL PAPERS PREPARED BY PARTICIPANTS FOR THE WORKSHOP

OPENING REMARKS AND WELCOME

Ernest Ambler, Ph.D.
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Good morning, and welcome to the National Bureau of Standards. I appreciate your coming here to discuss the future of our laboratory accreditation activities. This is an important topic to us at NBS, as it certainly is to you. Together, I hope we can formulate a rational, responsive set of proposals that serves the Nation well in this field of laboratory accreditation.

I hope we all agree with what we mean when we speak of laboratory accreditation. The term "accreditation" as defined by the ISO Standards Committee Ad Hoc Group on Definitions Required for Laboratory Accreditation Purposes, means "a formal recognition that a testing laboratory is competent to carry out specific tests or types of tests."

Laboratory accreditation plays a significant role in fostering and promoting domestic and international trade and commerce. The reasons for such a role are relatively simple and straightforward. We know that testing products before they are marketed has a high priority. Purchasers want to be assured that the items they purchase will do what the manufacturers of those items say they will do. Likewise, manufacturers want to be confident that their products will perform according to overall designs and objectives, and that they meet various standards. U.S. industry wants accreditation on a reciprocal basis to allow U.S. test results to be accepted in overseas markets.

You won't be surprised to hear that our efforts in the laboratory accreditation area are quite limited by available funding. This is not to our liking, but in today's budget climate major expansion is very unlikely. An obvious, and indeed the best, way to increase our effectiveness is through close cooperation with private sector work in laboratory accreditation. This workshop was called to help define areas of more effective cooperation between NBS and the private sector and particularly in direct response to the requests of the American Association for Laboratory Accreditation and the American Council of Independent Laboratories.

The United States is a pluralistic society in which institutions must work together. Government cannot--should not--attempt to solve every problem alone, whether that problem be inflation, foreign trade, or laboratory accreditation. Rather, the Government should help support the implementation of the good ideas and directions of the private sector, provided they are in the overall public interest.

Cooperation in this way and to this end has been the cornerstone of NBS activities since our founding 80 years ago. Let me cite some examples:

The private sector standards community has always had a strong supporter in NBS and vice-versa. Over 500 of our staff members now serve on more than 1300 national and international standards committees of about 125 organizations. We participate in both policy and technical activities related to standards. For example, in the policy area, the Director of NBS has been represented on the board of the American National Standards Institute since its inception, and before then, we worked closely with ANSI's predecessors: The United States of America Standards Institute, American Standards Association, and American Engineering Standards Committee. We have also had senior staff members on the boards of groups such as the American Society for Testing and Materials; the American Nuclear Society; the American Society of Heating, Refrigerating, and Air Conditioning Engineers; and the National Fire Protection Association. We also participate, in the national interest, in international organizations such as the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). Our purpose is to support the private sector standards working groups by bringing to bear our expertise in measurement and testing procedures.

Also in the international arena, NBS manages U.S. responsibilities in the Organisation Internationale de Metrologie Legale (OIML). OIML is an international group concerned with legal metrology. Its aim is to harmonize regulations among 47 member nations, with the objective of promoting free trade. NBS works closely with the States and with manufacturers of measurement equipment to arrive at agreements that allow our products to be freely sold in the world markets.

In more recent times, 1961 to be exact, we helped found the National Conference of Standards Laboratories, a group we continue to sponsor and work with. This organization of private, corporate, and government measurement laboratories helps us better understand current measurement needs. Such knowledge permits us to tailor our services to those needs. They also alert us to new technological developments that may well lead to new measurement requirements. In the other direction, they provide a very effective mechanism for the diffusion of measurement techniques and technology developed at NBS.

Back in the mid-1960's the Lamp Testing Engineers Conference faced a major measurement problem. The measurements used to rate lamps often varied by a factor or two from lab to lab. When you consider the huge market for light bulbs of all types, this was a major problem. They asked us for help, and we provided standards and methodology that reduced measurement uncertainty to 5 percent for most lamps.

Our cooperation in this area has grown substantially with the formation of the Council of Optical Radiation Measurements. This group of people from industry has been most helpful to NBS in evaluating our technical strategies for dealing with measurement problems in optical radiometry.

One NBS program that is changing industrial measurement practice is our work that permits the use of certain commercial detectors for absolute measurement of the quantity of light. We have also established a measurement assurance program through which outside laboratories are improving their measurement of retroreflectance.

Another example of our cooperative efforts is the National Conference of States on Building Codes and Standards. This group was formed with our help in 1968 to eliminate problems arising from the multiplicity of building code requirements, particularly those encountered in going from one State to another. We act as a technical resource to the group and have helped Massachusetts develop a building code for the rehabilitation of older structures.

For 60 years NBS has cooperated with industry in what we call the Industrial Research Program. In this program, scientists and engineers from industry work in our labs for a year or two on problems of mutual interest. Right now we have over 100 Research Associates at NBS, working in such diverse areas as automation, dental materials, the global satellite positioning system, and phase diagrams for metallurgists.

One of our major efforts in the measurement area involves standard reference materials. These are materials which we certify as to composition or physical property and which are used to calibrate measurement equipment in situ. Over 1000 different materials are sold by NBS, each meeting an expressed measurement need. For example, ASTM has several Research Associates working at NBS on the preparation of reference materials needed by the metals industry. We also work closely with medical and environmental groups in defining measurement needs and preparing appropriate reference materials.

Let me summarize by saying it is the job of all our technical staff to interact with the private sector in determining your needs and in shaping responsive NBS programs. We value particularly the opportunity to work with institutions such as I have mentioned; also with trade associations, professional associations, and so on. This leads to greater efficiency and effectiveness, and in our pluralistic society turns out to be an absolute necessity.

A very pertinent question is, "What does NBS have to offer in the field of laboratory accreditation?" My answer is that we are a scientific and engineering laboratory whose stock-in-trade is measurement expertise. We operate under legislation that makes us responsible for the Nation's measurement system. We are widely recognized, both in this country and abroad, as a first rate, credible organization, with no affiliations or biases that interfere with our quest for objectivity. Finally, we have a long and successful history of working with the private sector.

At this meeting we seek your opinions on the future of laboratory accreditation in the same spirit as exists in the cooperations I just described.

Thanks again for coming, and have a productive meeting.

Session 1

MEANING OF ACCREDITATION AND CERTIFICATION

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ABSTRACT - The common aspects of laboratory accreditation and product certification as these two terms are commonly used, as well as characteristics of each which delineate their distinctively different functions, are described. An understanding of the differences in the functions of each when applied to a system operation is essential if users of such systems are to appraise properly their significance.

The confusion or lack of complete understanding of the meaning of "certification" and "laboratory accreditation" exists at both the national and international levels.

Both the International Organization for Standardization (ISO) and the International Laboratory Accreditation Conference (ILAC) have recognized the "confusion" problem and have taken steps to deal with it by establishing an ILAC/ISO Ad Hoc Committee to deal with definitions and how to measure technical competency. This Committee has agreed upon a number of definitions which will be used in this discussion. These definitions are now being processed through the approval mechanisms of each organization and it is expected that these definitions will be adopted by both groups.

Definitions Applicable to Laboratory Accreditation

Testing laboratory: A laboratory which measures, examines, tests, calibrates, or otherwise determines the characteristics or performance of materials or products.

Laboratory accreditation: A formal recognition that a testing laboratory is competent to carry out a specific test or specific types of tests.

(Two notes to the definition are not included.)

Laboratory accreditation system: A system having its own rules of procedure and management for carrying out laboratory accreditation.

Accrediting body: A governmental or non-governmental body which conducts and administers a laboratory accreditation system and grants accreditation.

Accredited laboratory: A testing laboratory to which accreditation has been granted.

Accreditation criteria: A set of requirements used by an accrediting body which a testing laboratory must meet to be accredited.

Definitions Applicable to Certification

Conformity certification: The action of certifying by means of a certificate of conformity or mark of conformity that a product or service is in conformity with specific standards or technical specifications.

Mark of conformity: A mark attesting that a product or a service is in conformity with specific standards or technical specifications.

Certificate of conformity: A document attesting that a product or a service is in conformity with specific standards or technical specifications.

Certification system: A system having its own rules of procedure and management for carrying out conformity certifications.

Certification body: An impartial body, governmental or non-governmental, possessing the necessary competence and reliability to operate a certification system and in which the interests of all parties concerned with the functioning of the system are represented.

Third party certification system: A certification system managed by a certification body or under its surveillance.

From these definitions, it appears quite clear that laboratory accreditation is oriented to "testing competence" whereas product certification is "product conformance" oriented. While certification is also dependent upon the technical competence and reliability associated with the testing function in determining a product's conformance with the applicable standard or technical specification, it involves many other features as well.

Certification is concerned not only with confirming that a product complies with the applicable standard, but is also concerned with the materials, assembly, design, and features of production that relate to the manufacture of a uniformly complying product. Accreditation relates to the ability of a laboratory to conduct specific tests. It is not related to the manufacture, marking, or continuing complying production of any specific product.

In the ISO publication, "Certification - Principles and Practice," eight different types of certification are identified and it is suggested that there are probably still other versions in use.

So while the term "certification" seems simple and clear, certification systems are not by any means uniform in either their structure or operation. One must be very careful, therefore, when using the term "certification" that he further elaborates certain parameters of the system to adequately describe the mechanism about which he is speaking. Table I tabulates those characteristics of the eight certification systems described in the ISO pamphlet.

A similar problem is encountered when one looks at existing mechanisms identified by the term "Laboratory Accreditation Systems." In the ILAC publication, Directory of National Testing Arrangements and Testing Laboratory Accreditation Systems, one will find numerous deviations in the data furnished by various countries which reported compliance with an identified list of criteria established by the ILAC Task Force responsible for compilation and approval of the directory. As a matter of fact, laboratory accreditation by government or quasi-government groups is relatively new to the extent that it was necessary to devise a number of category headings in order to accommodate the different methods by which the recognition by government groups of laboratories to perform certain functions had been established.

In both laboratory accreditation and product certification the concept of an initial assessment and a form of follow-up service is embodied.

> In laboratory accreditation, the initial assessment is with respect to the technical competence of the laboratory to perform specific tests or types of tests. In product certification, the initial assessment is with respect to a product's conformance to a specific test and with respect to the manufacturer's ability to produce a complying product on a continuing basis.
>
> In certification, the follow-up will generally include an audit of the manufacturer's quality control program that relates to compliance. In laboratory accreditation, the follow-up will generally include a review of the initial technical assessment process and some form of proficiency testing.

In both processes, accreditation and certification are most generally carried out by third parties.

Certification bodies and accreditation bodies generally publish in the form of lists or pamphlets the names of manufacturers or laboratories which are covered under their procedures.

Laboratory accreditation may not require testing of specific products but rather requires evidence of the availability of adequate personnel, equipment and knowledge of testing procedures at the accredited laboratory. Certification involves some form of confirmation testing of a product against a specific standard, plus an affirmative judgment that the manufacturer has the necessary personnel, equipment and procedures to produce the product on a continuing uniform basis.

In certification, evidence of product compliance is generally by the use of a registered mark of the certification body on the certified product or its package. Evidence may also be provided in the form of a certificate. In laboratory accreditation, evidence of an accredited laboratory may be provided by use of the logo of the accredited organization on the information sheets that the manufacturer uses to record the test results.

Table II records some of the differences between laboratory accreditation and third party product certification that relate to those aspects of each system by which a degree of product conformance might be imparted. It is assumed that an assurance of product conformity might be a necessary ingredient in many transactions involving the trading of goods at both the domestic and international levels.

TABLE I

TYPES OF CERTIFICATION SYSTEMS (ISO)

	Forms of Testing		Forms of Follow-Up Action				
Type No.	Type Test	Assessment of Routine Testing	Testing of Open Market Samples	Testing of Factory Samples	Assessment of Factory Quality Control	Approval of Factory Quality Control	Audit of Quality Control
1	X	-	-	-	-	-	-
2	X	-	X	-	-	-	-
3	X	-	-	X	-	-	-
4	X	-	X	X	-	-	-
5 (1)	X	-	X	X	X	X	X
6	-	X	-	-	X	-	-
7	Batch (2)	-	-	-	-	-	-
8	100%	-	-	-	-	-	-

(1) Type of certification usually used by third party certification bodies.

(2) Sample selection and testing procedure employed such as to determine compliance of batch with specified requirements.

TABLE II

	How Related To	
Aspect or Element of System	Third Party Certification System	Laboratory Accreditation System
Product standard or technical specification	Certification is to the specific product standard	Laboratory is accredited to perform specific tests or groups of tests - Not necessarily to a specific standard nor to all the requirements of the standard
Technical competency	Covered in respect to a specific standard or technical specification	Covered in respect to specific tests, areas of testing, or disciplines, but not necessarily to a specific standard or technical specification
Impartiality	A requirement for the certification body operating the system	Not required by the system - Evaluation optional
Type testing of product	Required by the system	Not a part of accreditation criteria
On-going production testing	Covered by the system	Not a part of accreditation criteria
Batch or lot testing	Covered by the system	Not a part of accreditation criteria
Proficiency testing	Not required by the system	Generally required by the system
Independence of party conducting product testing	Required by the system	Not required by the system
Mechanism for relating evaluation to specific product or product manufacturer	Required by the system	Not a part of accreditation criteria
Use of mark of conformity	Required by the system	Not applicable
Published evidence of product conformance	Required by the system	Not required by the system
Procedure for notifying public when its mark is applied to an unauthorized product, or on a product found to be subsequently hazardous."	Required by the system	Not a part of accreditation criteria
Ability to verify product conformance through marking	Verification of product bearing mark of conformity	Not applicable
Procedures to evaluate quality assurance program for product	Required by the system	Not applicable
Reassessment of a laboratory's ability to conduct specific tests	Continuous reassessment by system operation	Required by the system
Procedures for monitoring factory quality control of product	Required by the system	Not covered - Reassessment of a laboratory's ability to conduct specific tests is made periodically
Procedures for corrective action	Required by the system	Required by the system
Extent of legal exposure	Proportional to volume and use of product bearing mark of conformity of certification body	Related to extent of public reliance and use on accreditation system, but lack of use of marking greatly reduces potential liability
Legal commitment of manufacturer of product	By use of mark of conformity on product required	Not applicable
On-site Inspection	Required by the system	Required by the system

In areas where there is a commonness of concepts in requirements, there is frequently deviation in the extent or area involved. For example, as regards technical competence, a certification system requires compliance with all aspects covered by a standard whereas laboratory accreditation may relate only to specific test methods.

In the area of product testing, a certification system would require at least a form of type testing of the product, whereas a laboratory accreditation system may not require any actual hands-on demonstration of product testing, but would rely upon an assessment of technical competence, plus successful performance in a form of proficiency testing which lends itself readily to measuring of specific characteristics of materials, but is likely to encounter severe problems when related to complex and expensive technical products.

Another difference between product certification and laboratory accreditation is the mechanisms available to inform the public concerning the results of testing and examination. The use of the accreditation body's logo in test report sheets are at best useful only with sophisticated users whereas the use of certification marks on certified products is at the heart of the product certification system.

Laboratory users who wish a third party assurance that a laboratory possesses the technical competence to perform certain specified tests may choose an accredited laboratory. Many laboratories, on the other hand, may not require this additional appraisal in order for their findings to have a high degree of acceptance.

By the same token, product certification by a third party may be desired by many users, purchasers and governmental authorities as further evidence of product compliance with specific requirements. Not all products, however, require such certification in order to have a high degree of acceptance. Most national certification programs have operated without any formal laboratory accreditation being required as a prerequisite of acceptance of findings.

Many products are purchased and sold on the basis of their meeting certain laboratory tests prescribed by the purchaser or required by the regulatory authority. Where compliance with such tests needs to be associated with specific batches or lots of product, laboratory accreditation may be a useful tool in facilitating the acceptance of the test results.

Where purchasers wish or regulatory authorities require a third party opinion as to compliance of ongoing production with all the requirements of a specific standard, together with a viable mechanism for identifying complying production, coverage under a third party certification system would seem to offer the best assurance of meeting such objective.

HISTORY OF LABORATORY ACCREDITATION IN THE U.S.

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Abstract: The chronological order of establishment of seventy laboratory accreditation programs is presented, including their motivation and scope of testing interest. Characteristics and historical trends of these accreditation programs are discussed with particular attention given to programs designed to serve large and/or general needs for laboratory evaluation and accreditation.

INTRODUCTION

A comprehensive history of testing laboratory accreditation in the U.S. would be a formidable task. One would need a reference library of the background and establishment of not only all existing accreditation programs but also those programs that may have been active in the past and that may have now passed from the scene. It is questionable that such a compendium of historical data would be of interest to many, or that it would assist the purposes of this workshop, except as a source for analysis of a characteristics and historical trends regarding laboratory accreditation in the U.S.

Mr. Charles W. Hyer, of the Marley Organization, undertook the identification and description of U.S. laboratory accreditation programs in 1978. His report, "Principle Aspects of U.S. Laboratory Accreditation Programs," was published by the Department of Commerce in January 1979. The information contained in that report was validated by authorities for the various accreditation programs described and has since been expanded and updated to July 1980 by Commerce's Office of Product Standards Policy, assisted by Mr. Hyer. This updated report, published by the National Technical Information Service (NTIS PB80-199086, July, 1980), serves as the primary reference source for this paper. Although the report is liberal and informal regarding selection of programs termed as laboratory accreditation activity and although the report is admittedly incomplete as to identification of all programs that may exist, the report provides a good basis for detecting characteristics and historical trends of laboratory accreditation in the U.S.

This paper lists in an appendix the chronological order of establishment of seventy programs identified in the revised Hyer Report. The appendix listing also shows the probable motivation and the scope of testing interest for each program, based primarily upon information contained in the referenced report. The paper classifies laboratory accreditation programs into two types, based upon their motivation and attempts to show differences among the types of program in regard to their characteristics, trends, and impact.

As the National Voluntary Laboratory Accreditation Program (NVLAP) and the more recently established American Association for Laboratory Accreditation (AALA) have a goal and objective to serve overall needs for laboratory accreditation, these programs are not easily classified in terms of motivation. As AALA's and NVLAP's policies for responding to the needs for laboratory accreditation are different and as NVLAP's original plan was similar to that to be implemented by AALA, a brief history of the evolution of NVLAP's policy and procedures is given.

A Classification of Laboratory Accreditation Programs

To paraphrase an old adage, behind every successful accreditation program there is a good motivation. A good motivation inspires testing laboratories to seek accreditation and encourages laboratory users to utilize such laboratories. Motivations for accreditation programs appear to be of two basic kinds which, I suggest, lead to two types of accreditation programs having characteristic differences.

One kind of motivation derives from product verification needs. I have labeled accreditation programs resulting from this kind of motivation "Type I," and have so referenced such programs in the appendix listing. The principal parties served by such an accreditation program are the motivator of the program and those who must have their products verified, namely the laboratory users. The viewpoints, opinions and needs of the laboratory community may be secondary to those of the principal parties in the establishment of these product verification programs. Laboratories are generally involved only to the extent that they are needed and seek accreditation by demonstrating their capability to meet the specific requirements for testing established by the program.

The other kind of motivation develops from a need to verify testing services for use by general classes of laboratory clients or by laboratory users having varied needs for testing. Accreditation programs resulting from this kind of motivation are labeled, "Type II." In these testing service verification programs, the testing laboratory constituency generally have a prominent or equal voice in establishing the scope, content, standards and procedures for accreditation.

Characteristics of Type I Programs

Fifty-four of the seventy accreditation programs listed are classified as Type I, or product verification programs. Their rate of growth since the thirty's is illustrated by the number of new programs established in each of the following decades.

Decade	New Programs
1931-40	1
1941-50	3
1951-60	1
1961-70	20
1971-80	29

Eight programs established in the sixty's are alike. They are state and local government mandatory programs for electrical product manufacturers and suppliers. It is suggested that these programs have a common source: namely, regulations referencing the National Electrical Code, section 906 which recommends use of "nationally recognized" testing laboratories. In the absence of a national authority for recognition of testing laboratories it is likely that these programs were established to fill the void and are essentially one program operated by several states. Excluding this anomoly one may conclude that there has been an exponential growth of Type I programs in recent decades.

Typically, the laboratory user constituency of Type I programs are product manufacturers, but there may be others in the production-marketing chain, such as growers, domestic shippers, exporters and importers, packing houses, building contractors or officials. Such laboratory users are motivated to use accredited laboratories (their own or others) by federal, state, or local product regulations, by product certification programs and procurement protocols, by international trade arrangements and by trade association product quality programs. Typically, the motivation requires or encourages the laboratory user (such as a manufacturer) to supply particular products to a defined specification, compliance to be determined by an accredited laboratory using referenced test methods. The accrediting authority for the laboratories is usually an organizational part of the entity that promulgated the motivation.

Several characteristics of these Type I accreditation programs demonstrate that the thrust of the programs is directed toward manufacturers and other product suppliers that are the laboratory users. For instance, the laboratory user constituencies of many of these programs must comply with government or private sector mandates to use accredited laboratories; however, essentially all of the Type I accreditation programs established between 1931-1980 depend upon the voluntary participation of testing laboratories.

The reliance of Type I accreditation programs upon voluntary participation of testing laboratories would normally not seem to be a significant concern to laboratory users required to use their services. Laboratory users such as manufacturers would merely need to pressure their in-house laboratories to obtain the needed accreditation. However, another common characteristic of Type I accreditation programs comes into play. Of the fifty-four Type I accreditation programs reviewed, twenty-eight programs also require the testing laboratory to be independent of the laboratory user. Of the programs listed, it appears that the first program to require such independence is Dade County's program for laboratories testing building products, established in 1957. Thus, Type I programs, relying upon voluntary participation of laboratories, depend to a significant extent upon commercial, independent testing laboratories that are not subject to the authority of the motivator, accrediting agency, nor the laboratory user. The reason for such laboratories to participate must be their interest in attracting and serving their clients. In this sense, Type I programs are essentially user-oriented programs.

Another significant characteristic of Type I accreditation programs relates to the costs of being accredited. Of the fifty-four Type I programs, thirty-eight impose no fees upon the laboratories. The Department of Agriculture program for grain inspection, started in 1940, seems to be the first Type I program to establish a no-fee policy. Costs of accreditation are borne by the accrediting authority or, in a few cases, by the laboratory users. In three other programs, the applicant laboratory is charged fees only for its initial evaluation and accreditation. Only in twelve of the fifty-four Type I programs are laboratories required to pay continuing fees for their accreditations and renewals. Eleven of these twelve programs are conducted by accrediting authorities in the private sector. The only Type I government program charging fees to laboratories for their accreditation is the Massachusetts program for the testing of solid fuel heating appliances, initiated in 1978.

Finally, it appears that several Type I programs do not consider it a right of laboratories to be accredited when such a service is provided. There is an indication that Type I programs frequently limit accreditation to only those laboratories required to serve the objective of the program; such as to assure that sufficient accredited laboratories exist to serve the requirements imposed upon laboratory users. The available information on accreditation programs is insufficient to adequately quantify this characteristic, but it is evident that many Type I programs will not consider all laboratories that may wish to apply. For instance, some accrediting authorities may limit the number of accredited laboratories within a geographical area, or require evidence that the laboratory is called upon to test the product in question. Other programs accredit laboratories on a case-by-case basis only as they are identified in product procurement negotiations and the like.

In summary, Type I accreditation programs, whose usual objective is to assure that accredited laboratories exist to serve product assurance requirements imposed upon laboratory users, generally rely upon the voluntary participation of testing laboratories. Participation is frequently limited to commercial laboratories or other laboratories that are independent in relationship to the laboratory user. Other limitations, related to restricting accredited laboratories to those needed to serve the programs' objectives are sometimes imposed. Costs of accreditation services are usually borne by the accrediting authorities for government programs and by the participating laboratories in private sector programs.

Characteristics of Type II Programs

Fourteen of the seventy accreditation programs listed in the appendix are classified as Type II, or testing service verification, programs. The growth of new programs in the decades since the thirty's is shown in the following table and is noted to be approximately linear since 1960.

Decade	New Programs
1931-40	1
1941-50	1
1951-60	2
1961-70	5
1971-80	5

Motivations behind this type of program are directed toward the laboratories rather than the laboratory users as in Type I programs. Typically, the laboratory constituency of these programs is public health laboratories, environmental laboratories, clinical laboratories and product testing laboratories that provide testing services directly to the public or to the government. Such laboratories are motivated to obtain approval by licensing or certification regulation, by government protocols for procurement of testing services and by peer group qualification programs. The motivation usually requires or encourages the laboratory to provide for defined disciplines, facilities, personnel, and equipment having particular qualifications; however, sometimes certain product testing competencies are specified. Similar to Type I programs, the accrediting authorities for Type II programs are usually an organizational part of the entities that provide the motivation.

Eight of the fourteen programs listed as Type II are mandatory in nature. Five mandatory programs, established in 1932, 1950, 1960, 1977, and 1978, derive from state requirements for licensing of laboratories that provide testing services for public health and for environmental, water, food, and concrete analysis. Two programs established in 1966 and 1969 serve federal licensing and certification requirements for clinical testing supporting Medicare and involving interstate commerce. One 1973 program of mandatory nature established by the National Electrical Testing Association requires accreditation for membership in its peer group association. Of the seven government mandatory programs for testing laboratories, only one imposes fees upon the laboratories for their accreditation (licensing): the Massachusetts program for concrete testing laboratories, initiated in 1978.

The remaining six Type II accreditation programs are voluntary in nature. Five of these programs are motivated by peer group associations or by federal procurements of testing laboratory services. The other program, started in 1951, derives from a federal-state activity to promote the quality of milk and milk products in interstate commerce. Of the six voluntary Type II programs, four impose fees upon the laboratories for their accreditations. The two voluntary programs that do not charge fees are both federal government programs.

Of the fourteen Type II programs listed, only two programs restrict accreditation to independent laboratories. Both programs accredit laboratories that seek to provide product testing services to the federal government in support of procurement activities. These two programs are also the only Type II programs that limit accreditation to laboratories on the basis of need for laboratory services.

To summarize, the Type II accreditation programs, whose usual objective is to assure that adequate testing services exist to serve the public or the government, frequently mandate the participation of testing laboratories subject to their authority. Participation of testing laboratories in mandatory and voluntary forms of Type II programs is usually open to all interested testing laboratories, regardless of their organizational structure or the public need for their services. As with Type I programs, costs of Type II accreditation programs are usually borne by the accrediting authorities in government programs and by participating laboratories in private sector programs.

Although the National Voluntary Laboratory Accreditation Program (NVLAP) and the program of the American Association for Laboratory Accreditation (AALA) are included in the appendix listing they have not been considered in the classifications of programs discussed above. On the basis of some knowledge of the present NVLAP and the goals and objectives of AALA I believe that both desire to provide for Type I and Type II accreditation programs if their policies and procedures can be harmonized with the needs for accreditation as exemplified by some of the accreditation programs shown in the listing.

IMPACT OF LABORATORY ACCREDITATION PROGRAMS

Most accreditation programs reviewed provide accreditation to less than one hundred laboratories. A few programs serve as many as five hundred laboratories. In total, the fifty-four Type I programs reviewed serve approximately four thousand laboratories. By comparison, those Type II or testing service verification programs that serve the clinical laboratory community are gigantic. About thirteen thousand clinical laboratories require licensing or certification, a mandatory form of accreditation, due to their involvement in interstate commerce or in serving Medicare patients. Some six thousand of these laboratories enjoy recognized accreditation status due to their being parts of hospitals accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association. The remaining eight thousand laboratories are subject to the authority of Type II programs identified in the appendix; namely, the College of American Pathologists Program, CAP, established in 1962; the Federal Health Care Finance Administration Program, HCFA, for laboratories serving Medicare, initiated in 1966; and the HCFA program for laboratories involved in interstate commerce, established in 1969.

The initial motivation for the CAP program was to foster laboratory improvement through a voluntary peer review process. However, by 1967, the CAP accreditation program was sufficiently known and respected to be designated in the federal Laboratory Improvement Act. By 1981, this voluntary program was accrediting for fees, approximately 2400 laboratories, CAP's Commission on Laboratory Accreditation has a chairperson and ten regional commissioners appointed by the president of the College. The Commission's major functions are to review and maintain the standards, act on new and problem areas, and formally approve accreditation actions. Several resource committees of the College may be called upon to provide technical advice.

Each of the regional commissioners is assisted by commissioners for the states. Their major duty, in addition to recommending accreditation actions to the full Commission, is to assist in recruiting, training and assigning inspectors. Inspectors are board-certified pathologists who have previously accompanied experienced inspectors or who have received indoctrination in periodically held workshops. Inspectors, in turn, recruit from their geographical regions appropriate specialists to form their on-site teams, chosen with regard to the nature of the laboratories to be visited.

From the program's standards that address requirements for safety, quality control, equipment, personnel, laboratory environment and facilities, updated computerized inspection checklists are maintained to assure that requirements are met uniformly. A major requirement for accredited laboratories is successful participation in proficiency testing programs offered by the College. Semi-annual summaries of results are reviewed by the regional commissioners thus providing a means for monitoring accredited laboratories' performance. Accreditations are renewed on a biennial basis.

The federal accrediting authority for clinical laboratories is HCFA. Two programs are administered and coordinated by HCFA. One program initiated in 1966 provides for the certification of clinical laboratories that receive federal payment for services to Medicare-Medicaid patients as required by Social Security legislation. Title 42, USC, 1395 requires such laboratories to be certified as meeting the requirements established by the Secretary. HHS, or to be accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association, subject to their standards being deemed equivalent. As noted, JCAH and, AOA accredit approximately six thousand hospitals, including their laboratories. Under this program HCFA certifies an additional five thousand clinical and hospital laboratories.

The other program, initially established in 1969 by the Center for Disease Control and now administered by HCFA, provides for the licensing of clinical laboratories serving in interstate commerce as required by the Laboratory Improvement Act of 1967. Title 42, USC, 263 directs that private clinical laboratories, not part of a hospital or a doctor's office and participating in interstate commerce, must be licensed for compliance with federal requirements or be accredited by the College of American Pathologists, subject to their standards being deemed equivalent. Under this program HCFA licenses about one thousand clinical laboratories. An additional one thousand laboratories accredited by CAP submit their accreditation in lieu of licensure.

Upon transfer of the interstate laboratory program to HCFA in the mid 1970's, HCFA coordinated the administration of the two clinical laboratory programs. A federal headquarters office develops rules, coordinates with recognized accreditation authorities such as CAP, acts on problem areas and assures effective monitoring of the programs. Ten federal regional offices, each with a coordinator and an inspector, carry out the federal field responsibility. Fifty state government offices, supported by federal funds, conduct the bulk of inspections. Use of a standard inspection report form, HCFA 1557, provides for uniform inspections. This form reiterates and details federal regulations promulgated under 42CFR405. Under these criteria laboratories are required to comply with state and local laws. Other criteria apply to personnel, management, proficiency testing and quality control procedures. Laboratories may qualify for one or more disciplines (nine in number; e.g., microbiology, pathology, chemistry), or for subspecialties within these disciplines. Specific criteria for these disciplines and subspecialities relate to proficiency testing and quality control procedures. Recommendations for accreditation action are forwarded by the state inspection agencies to HCFA which grants or denies license or certification. Required proficiency sample programs are provided by the Center for Disease Control or are those reviewed and approved by CDC and HCFA. Laboratories are reexamined on an annual basis.

In the mid 1970's increasing public criticism regarding the services of clinical laboratories led federal authorities to establish additional requirements for validation of laboratory inspections. Presently, clinical laboratories must allow entry of examiners upon request for purposes of validating the laboratories' last inspections. Programs whose accreditations are recognized in lieu of federal license or certification, must require agreement of their laboratories to allow entry of government examiners for purposes of such validation. In addition, the fifty state agencies must permit review of their operations by federal authorities. Two or three state agencies are reviewed each year. The inspection of approximately eight hundred laboratories are validated each year, divided equally among laboratories that are accredited and those that are licensed or certified.

ACCREDITATION PROGRAMS FOR THE GENERAL NEED -- AALA AND NVLAP

In its planning state the National Voluntary Laboratory Accreditation Program (NVLAP), established in 1976, evolved from a government-private effort to accredit laboratories for classes of technology to a government program that accredits laboratories on a product-by-product basis or an associated service basis where the product or the service is defined by standards and test methods. In its present form NVLAP could have difficulty in establishing the kinds of Type II accreditation programs where the technical discipline to be served is not defined regarding the standards and test methods to be employed. The American Association for Laboratory Accreditation (AALA), established in 1978, retains the original intent of NVLAP to accredit laboratories on the basis of broad technical competences. With this policy AALA could have trouble in establishing those kinds of Type 1 programs that are concerned with specific products, specifications, and test methods. As will be shown in another paper the problems of accommodating interest in specialized accreditation and interest in more generalized accreditation are not unique to the testing laboratory field. It appears that users of accredited institutions favor specialized accreditation programs. Institutions subject to accreditation prefer accreditation for broader areas. As NVLAP's original plan was similar to that of AALA's and was then revised, a brief history of NVLAP's establishment should be reviewed.

Around a decade ago, various interests saw the need for a nationally based program to serve the general need for evaluation of laboratories. A conference of some 150 representatives from approximately sixty federal, state and private organizations and agencies met at the National Bureau of Standards, NBS, in September 1970 to consider the need and viability of a national program for evaluation and accreditation of laboratories.

An ad hoc committee, established by the conference and consisting of leaders in the standards, laboratory, product certification and procurement communities, completed in December 1970 a "Concept of a National System for Laboratory Evaluation and Accreditation." The concept visualized a private or quasi-public national board of accreditation composed of affected interests, the board to be assisted by technical and advisory committees from standards, laboratory and user communities. Government support in the form of technical, legal and financial assistance would be required. The system would provide inspection-evaluation of technical competences for fees to all laboratories upon their request, and on the basis of the results of such evaluations would provide accreditations to those laboratories that serve a general clientele or the government. At its last meeting in March of 1971 the committee declined to identify a lead organization for establishing the system; the committee recommended that NBS continue to focus interest in the system and its development.

The "Concept" document served as a focus of discussion by many interests in the period 1971-73. Many of these government and private sector interests met together at NBS in February 1973 and recommended the following:

- the system should be quasi-public;
- the system should have no regulatory power;
- no federal legislation should be enacted or encouraged;
- the system should serve primarily the needs of laboratories that serve the public or the government;
- the system should offer more than an assessment of technical capability, namely an assessment of ability to determine product conformance to recognized standards; and,
- criteria for judging performance of a laboratory should be established by existing standards-making bodies.

The group, in response to ASTM and NBS proposals, concluded that ASTM should accelerate development of laboratory evaluation criteria and that NBS, with approval and support of the Commerce Department, should look into various alternative ways of establishing the system: incorporation by an independent private body, a federal charter for a quasi-public entity, government establishment under a formal administrative rule.

Promulgation in September 1973 of controversial OSHA regulations for laboratory accreditation and Congressional letters in early 1974 endorsing and proposing legislation for a national system of laboratory accreditation stimulated greater interest of the private sector and federal agencies, particularly the Department of Commerce. With concurrence of the Office of Management and Budget, the Secretary of Commerce responded to Congressional inquiries in April 1974, announcing that the Department was considering the establishment of a pilot program capable of being extended on the basis of experience and need. Proposed procedures for a National Voluntary Laboratory Accreditation Program were published in the Federal Register in May of 1975. The proposed procedures provided for the establishment of laboratory accreditation programs for classes of technology on the basis of need, significant user constituency and identifiable product standards and testing functions. For each laboratory accreditation program, a board of accreditation composed of federal employees aided by an advisory committee of private individuals, would identify standards, and evaluation criteria and examine qualifications and recommend accreditation actions for evaluated laboratories. Thereafter, the proposed procedures were revised in two major aspects in response to extensive public comment:

- laboratory accreditation programs for classes of technology were deleted in favor of programs for specific product and associated service areas. Many public comments stressed the importance of establishing laboratory accreditation programs only for well defined needs. The public comments illustrated that needs varied for different products within a class of technology, thus making a justification of need unlikely across an entire class of technology; and,
- boards of accreditation of federal personnel aided by advisory committees of private individuals were deleted in favor of a single advisory committee for each laboratory accreditation program. The advisory committee would be composed of government and private individuals and would function to develop and recommend criteria for the accreditation of laboratories. Considerable public criticism concerned the lack of private individuals on the proposed board of accreditation. As some of the proposed functions of the boards of accreditation were operational rather than advisory or consultative in nature, the appointment of private individuals to the boards was not legally possible without enabling legislation.

Procedures for NVLAP were published in the Federal Register in February 1976 and NVLAP became an item in the federal budget in the following fiscal year. In recent years, formal actions have been taken to harmonize criteria for programs established under NVLAP and to allow for participation of all interested parties in the development of accreditation criteria. Optional procedures have also been promulgated for federal agencies seeking to establish NVLAP accreditation programs under their existing authority and for the private community which may wish to establish programs under NVLAP, having first justified the need in accordance with appropriate due process procedures.

APPENDIX

DATE	MOTIVATION	ACCRED. AUTHORITY	PRODUCT/SERVICE	PROGRAM CLASS
1932	Pa. Regulation for laboratories	Pa. Dept. of Agr.	milk, milk prods. testing	Type II
1940	Fed. Produce Reg.	U.S. Dept. of Agr.	grain	Type I
1946	Fed. Product Reg.	FAA	aircraft, equip.	Type I
1947	Trade Assoc. Prod. Certification	Natl. Safe Transit Association	packaging	Type I
1950	Prof. Society Prod. Cert. Prog.	ASME	safety valves	Type I
1950	N.Y. Regulation for laboratories	NYS Health Dept.	environmental testing	Type II
1951	Fed-State Agree.	FDA	milk testing in interstate	Type II
1957	County Bldg. Code	Dade County, Fla.	building products	Type I
1960	Conn. Health Regulation	Conn. Dept. of Public Health	environmental and food testing	Type II
1961	DOD Procurement Protocol	DOD Personnel Support Center	mainly textiles	Type I
1962	Fed. Meat Regs.	U.S. Dept. of Agr.	meat and poultry	Type I
1962	DOD Procurement Protocol	Defense Electronic Supply Center	electronics	Type I
1962	Trade Assoc. Prod. Cert. Program	Air Diffusion Council	air diffusion equipment	Type I
1962	Prof. Society Peer Review	College of American Pathologists	clinical testing	Type II
1963	City Electrical Ordinance	Richmond, VA Elect. Department	electrical products	Type I
1963	Trade Assoc. Prod. Cert. Program	Architectural Alum. Manuf. Association	windows, storm doors	Type I
1965	City Electrical Ordinance	L.A. Dept. of Building	electrical products	Type I
1965	State Building Code	Washington State Elec. Inspection Division	electrical products	Type I

APPENDIX, PAGE 2

DATE	MOTIVATION	ACCRED. AUTHORITY	PRODUCT/SERVICE	PROGRAM CLASS
1965	State Building Code	Ohio Board of Build. Standards	building products and materials	Type I
1966	DOD Procurement Protocol	U.S. Corps of Engineers	construction matls.	Type II
1966	Federal Health Regulation	Health Care Finance Administration	clinical testing	Type II
1966	Private Product Cert. Program	Associated Laboratories, Inc.	insulating glass	Type I
1967	Trade Assoc. Prod. Cert. Program	Air Movement and Control Assoc.	air movement products	Type I
1968	Federal Procurement Protocol	NASA	aerospace products	Type I
1968	Federal Motor Vehicle Regula.	Natl. Highway Traffic Safety Administration	auto safety tests	Type II
1968	City Electrical Code	Portland, Ore. Elec. Department	electrical products	Type I
1968	Trade Assoc. Prod. Cert. Program	National Kitchen Cabinet Assoc.	kitchen cabinets	Type I
1969	Federal Procurement Protocol	General Services Administration	various products	Type I
1969	Federal Health Regulations	Health Care Finance Administration	clinical testing in interstate	Type II
1969	State Electrical Code	North Carolina Dept. of Insurance	electrical products	Type I
1969	City Electrical Ordinance	Atlanta, Ga Code Compliance Office	electrical products	Type I
1969	City Electrical Ordinance	San Francisco Electrical Dept.	electrical products	Type I
1970	City Electrical Ordinance	Chicago Bureau of Electrical Inspection	electrical products	Type I
1970	Trade Assoc. Quality Ass. Prog.	U.S. Potters Assoc.	ceramic products	Type I

APPENDIX, PAGE 3

DATE	MOTIVATION	ACCRED. AUTHORITY	PRODUCT/SERVICE	PROGRAM CLASS
1971	Prof. Society Prod. Cert. Program	Amer. Assoc. of Motor Vehicle Admin.	motor vehicle safety equipment	Type I
1971	Trade Assoc. Prod. Cert. Program	Safety Glazing Certification Council	glazing materials	Type I
1972	Prof. Society Qual. Assur.Prog.	Ohio Assoc. of Consult. Engs., Inc.	concrete materials	Type I
1973	Fed. Work Safety Regulations	Occupational Safety & Health Administration	various occupational use products	Type I
1973	Fed. Custom Regs.	U.S. Custom Service	petroleum	Type I
1973	Prof. Society Peer Review	American Industrial Hygience Association	chemical & biologic testing	Type II
1973	Trade Assoc. Qual. Assur.Prog.	National Electrical Testing Association	testing of electric power equipment	Type II
1974	State Electrical Regulations	Oregon Electrical Advisory Board	electrical products	Type I
1975	Federal Regulations	Federal Communications Commission	radio frequency emitting devices	Type I
1975	Federal Housing Regulations	HUD	mobile homes	Type I
1975	Model Code Ass. Qual. Assur.Prog.	Intl. Conference of Building Officials	building products and materials	Type I
1976	Federal Rule	U.S. Dept. of Commerce	various products & associated services	Type I & Type II
1976	Federal Food & Drug Regulations	FDA	food, drugs, and cosmetics	Type I
1976	Model Code Assoc. Qual. Assur.Prog.	Southern Building Code Conference	building products and materials	Type I
1977	DOD Procurement Protocol	Defense Logistic Agency	various products	Type I
1977	Federal Water Regulations	EPA	drinking water	Type I
1977	Federal Procurement Protocol	Intl. Assoc. of Chiefs of Police, Inc.	law enforcement equipment	Type I

APPENDIX, PAGE 4

DATE	MOTIVATION	ACCRED. AUTHORITY	PRODUCT/SERVICE	PROGRAM CLASS
1977	State Consumer Regulations	Florida Solar Energy Center	solar collectors	Type I
1977	State Regulations for laboratories	Kentucky Dept. of Natl. Resources & Envir. Prot.	testing of water	Type II
1977	Prof. Society Prod. Cert. Program	ASME	offshore oil & gas control equipment	Type I
1977	Trade Assoc. Prod. Assurance Program	North Carolina Board of Accreditation of Concrete Tstg.Labs.,Inc.	concrete	Type I
1977	Trade Assoc. Prod. Cert. Program	Insulating Glass Cert. Council	insulating glass units	Type I
1978	International Convention	U.S. Coast Guard	cargo containers	Type I
1978	State Product Regulation	California Energy Commission	solar collectors	Type I
1978	State Product Regulation	California Energy Commission	thermal insulation	Type I
1978	State Regulation for Laboratories	Massachusetts Bldg. Code Commission	concrete materials testing	Type II
1978	State Product Regulation	Massachusetts Bldg. Code Commission	solid fuel heating appliances	Type I
1978	Laboratory Assoc. Qual. Assur.Prog.	American Assoc. for Laboratory Accred.	various technical disciplines	Type I & Type II
1978	Model Code Assoc. Qual. Assur.Prog.	Building Officials & Code Admin. Intl.	building products and materials	Type I
1979	Federal Regulations	EPA	motor vehicle emission tests	Type I
1979	Federal Regulations	HUD	building products	Type I
1979	Federal Mining Regulations	U.S.Dept. of Interior Of. of Surface Mining	hydrological survey testing	Type I

APPENDIX, PAGE 5

DATE	MOTIVATION	ACCRED. AUTHORITY	PRODUCT/SERVICE	PROGRAM CLASS
1979	Federal Marine Regulations	U.S. Coast Guard	marine safety devices	Type I
1980	Prof. Society Qual. Assur.Prog.	Water and Wastewater Analyst Association	water testing	Type II
1981	International Prod. Cert.Plan	U.S. Natl. Committee of IEC	electronics in international trade	Type I
pro-posed	Product Cert.	Solar Energy Res. & Education Foundation	solar equipment components	Type I

STATUS OF LABORATORY ACCREDITATION IN THE UNITED STATES

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ABSTRACT - This presentation briefly describes the status of laboratory accreditation at the time of the publishing of the work "Principal Aspects of Laboratory Accreditation Systems", in July 1980. NVLAP, AALA, IEEE and IECQ systems are described to present updated information. The current and near future environment that does and will affect laboratory accreditation is discussed. The size of the problems to be addressed and a prediction of the possible outcomes and reasoning is offered.

FOREWORD

In recent years the subject of laboratory accreditation has evoked as much controversy as its sister subject of standardization and product certification. It has been the center for such confrontations as government versus private sector, commercial services versus restricted use in-house services,and so on.

Unfortunately a small percentage of the controversy concerning these subjects centers on anything remotely connected with the discipline of engineering. Rather it is the individual engineer or scientist seeking to protect his perceived economic involvement that has introduced adversary approaches to otherwise technical considerations.

This paper was prepared in an attempt to consider the subject of the current and near future status of laboratory accreditation. It was not prepared as a defense of the use of laboratory accreditation or even its existance. It was not prepared to influence anyone on any form or sponsorship of laboratory accreditation.

However, it was prepared with the bias that comes from the study of, and experience with the subject matter -- laboratory accreditation. In its preparation this paper became the guideline for a fifteen minute oral presentation that necessarily treats aspects of laboratory accreditation status but very briefly if at all.

If the reader will look upon this presentation as an attempt to offer some information on the status of accreditation and avoid considering it a definitive position paper than it may accomplish its intended purpose -- to fill a small area of information need, within the context of a complex controversial subject.

SOME DEFINITIONS AND BACKGROUND REFERENCES

In July 1980 the Office of Product Standards Policy of the U.S. Department of Commerce published its "Principal Aspects of U.S. Laboratory Accreditation Systems" [NTIS PB-199086]. This publication was a revision and expansion on the report "Principal Aspects of U.S. Laboratory Accreditation Programs" which we wrote under contract to Commerce and was published January 24, 1979. Our work for the second version was limited to the description of new "systems" or "programs." Both of these publications form an essential background reference for this paper.

Just as essential is a need to understand some of the factual operational procedures employed in providing the descriptions for these publications. Foremost among the facts is the agreement between the staff of the Office of Product Standards Policy and the writer as to what would constitute a "laboratory accreditation program" or "system" which should be identified and described. For this we should like to quote from a letter of instruction from the Contracting Officer's Technical Representative [COTR] Mr. Peter S. Unger, dated September 14, 1979.

> " 1. Provide a one-page summary for each newly identified laboratory accreditation program. (Note: A laboratory accreditation program is to denote a more or less formalized, ongoing method by which a laboratory is acknowledged, recognized, listed, approved, etc., as an acceptable or capable source to perform specified testing services by any private or public sector organization such as trade associations and Federal, state, and local government agencies.)

The key is that there was a conscious attempt on the part of the contractor to limit identifications and reports to those dealing with testing, with allied activities such as inspection, examination, etc. In so doing programs which accredit organizations by personnel, calibration capability, etc., or others intended to accredit R&D or other laboratory services were excluded.

Other exclusions such as private systems are explained in the introductions to these publications. However, it should also be mentioned that many reports were not published in keeping with the objections to publication expressed by the private sector and government agencies involved, after identification, by the contractor.

Another consideration that deserves mention is that the value of the work as a reference for "accreditation" is limited by the economic constraints of the contract supporting the work. It was not one which allowed for extensive survey work, but depended in large part on existing contractor information and expertise. However, to the present we know of no other single source of information on the subject which exceeds that available from The Marley Organization, Inc. as assembled by the writer.

Finally because of arbitrary decisions made by the writer in reporting to the Office of Product Standards Policy, both references are dominated by product certification related entries. This has proven to be most unfortunate. It has given rise to the belief that the descriptions of programs are in some manner details of the product certification programs themselves. While it is necessary to provide some certification program information in the description incorporating laboratory accreditation analysis, much more is needed to properly project the nature of the basic certification program. In addition there are product certification programs, too numerous to mention which rely on contractor laboratories, or are sponsored by laboratories themselves, without which no study of certification would be valuable. The situation has become more complicated in that some laboratory accreditation interests have approached product certification sponsors offering their programs as alternatives to existing methods of accrediting or contracting. To clear this matter some explanation is necessary.

Laboratory accreditation when applied to a specific product certification program's verification or validation methods is not a mutually inclusive or exclusive term. To explain by example may prove expedient. Many laboratories have the capability of testing for compliance to appropriate standards products that are covered by product certification programs. Accreditation for such laboratories may be desirable or essential. However, such accreditation should not be confused with validation or verification of certification. The entity performing such actions may in fact be neither a laboratory or in any manner accredited. On the other hand it may be possible for all accredited laboratories to offer verification or validation. It is in the terms of the certification program where clarification is found, not in the terms of the descriptions offered in either of the works referred to as "Principal Aspects of U.S. Laboratory Accreditation...."

To be very clear and specific there are two major laboratory accreditation programs under consideration at this conference. The National Voluntary Laboratory Accreditation Program of the Department of Commerce employs the evaluation capability of the National Bureau of Standards. The American Association for Laboratory Accreditation in the private sector is seeking commitments whereby Commerce, through NVLAP would have the NBS evaluate its, and other accreditation methods, leaving direct laboratory accreditation to accredited accreditors. In addressing current and future status of a laboratory we will be addressing accreditation for the general purpose of testing purposes, with its allied functions, not related to validation/verification functions in certification.

CURRENT STATUS OF ACCREDITATION

On October 19th the National Voluntary Laboratory Accreditation Program published its latest "finding of need" for a new program. This time the subject was acoustical testing services. In its new procedures NVLAP will now address needs of international and military documentation. More importantly it has grown with the experiences gathered in other accreditations. NVLAP now has the understanding that no matter how the criteria and evaluations are made, specific agreement among those to be accredited on technical issues relevant to each test method must be addressed and resolved. This is a burden which must be accepted by any accreditation program based on specific standards and test methods.

NVLAP proposals for requests are progressing in the area of personnel dosimeters, solid fuel room heaters, and electromagnetic calibration services. Each of these LAPs will, in its own way, add to the experience factors for accreditation evaluation. However, please note that programs such as dosimeters and calibration services were not envisioned at the time we wrote our accreditation description reports, intended to cover testing laboratory work. As a further commentary we are not at all sure that an attempt at the accreditation of solid fuel room heaters, even to specific requirements of HUD will be beneficial. The entire area of solid fuel room heaters is changing from hour to hour with voluntary standards, codes and regulations and may need some settling time before choice of test methods and standards are valuable and in the long run beneficial.

Organizations that are accredited by NVLAP currently are dominated by non-commercial entities. That is only a small percentage of accredited laboratories offer for a fee, the testing services for which they have been accredited. For this reason one sees little exploitation of accreditation. As the programs increase it may be expected that this will change and more commercial entities will feel a need or value in NVLAP accreditation.

The other accreditation organization, intended in scope to operate for the purpose of accrediting laboratories is the American Association for Laboratory Accreditation [AALA]. Intended operation is meant to remind readers that other than NVLAP and AALA all other accreditations that we have identified in current work have laboratory accreditation as a means to an end, such as product certification, while NVLAP and AALA are a means of identifying laboratories through accreditation of capabilities.

At the point of the latest publication on accreditation, July 1980 to current status, AALA has moved forward by light years. From an organization with wide, undefined methods of accrediting laboratories by vague discipline approaches it has moved to stability. From inception until sometime in 1980 one could read into AALA the intent to capture, for its membership, specific areas of product certification work, especially electric-safety related work. Now it has, possibly from the public reading of the very intent we suggest modified its positions.

Currently AALA has three disciplines available for accreditation purposes. However, its sub-sets of accreditation limit, while at the same time make more meaningful, each disciplines coverage. It has some seven organizations: Harris Laboratories, Lincoln, NE; Lancaster Laboratories, Lancaster, PA; PSE&G Research & Testing Labs, Maplewood, N.J.; Standard Laboratories, Knoxville, TN; Structure Probe, West Chester PA, NJ &CT; and Warner Laboratories, Cresson PA already accredited within the chemical discipline. With the construction materials testing and the electrical discipline LAPs available it is our understanding some 35 new organizations have either commenced the process of applying or have indicated future intent or plans to hold membership in the AALA organization. The latest extensive move has been attributed to renewed interest on the part of commercial laboratories, many members of the American Council of Independent Laboratories-ACIL. Please note that all but one of the current seven accredited organizations are members of ACIL and all are commercial testing firms.

While the NVLAP and AALA programs consititute a look at the current status of active accreditation programs two other entries with rather substantial impact have also been chosen for review. These are representative of current developments of major impact accreditation since July 1980.

The first is a program the details of which will be covered during an IEEE seminar on November 17 here in Washington, D.C. The sponsor of the laboratory accreditation is the Institute of Electrical and Electronics Engineers [IEEE]. The purpose of the accreditation is to accredit "...organizations undertaking environmental testing of safety-related equipment for use in Nuclear Power Generating Stations." The "Applicable Qualification Standards" are the "existing IEEE Standards for qualifying and testing motors, modules, cables, valve actuators and IEEE Standards under development on environmental qualification." Some of the criteria to be used includes the "IEEE Std. 603, "Standard Criteria for Safety Systems for Nuclear Power Generating Stations."

IEEE's accreditation while specific to nuclear licenses must be considered a major entry into this laboratory accreditation activity in that it will be employed by a sensitive regulatory agency as a means of reducing regulation. The intent is the elimination of multiple audits while improving testing consistency and uniformity to provide testing control and reliability of test results.

In our personal interview with IEEE officials it is estimated that from 80 to 150 initial applicants are expected. It is further expected that accreditations will range from design review professionals through complete testing services organizations.

The second program is the implementation of the IEC Quality Assessment System for Electronic Components. Three educational seminars to run December 1 in Washington, D.C.; December 2 in Chicago; and December 4 in San Francisco are planned.

While this is a product certification effort, it is national in scope and international in effect. The United States through the appointment of Underwriters Laboratories by The Electronic Components Certification Board has its own National Supervising Inspectorate [NSI]. It is the work of this NSI to qualify components and approve facilities in some 20 device categories, from resistors to relays for international acceptance. Laboratories of the manufacturers or those employed commercially for use by the manufacturers will be accredited.

One would do well not to look at this accreditation as one of narrow scope, affecting only international trade and only in the specific area of electronics. Not that that alone does not qualify this program for specific detailing. However, in the area of aerospace electronics and military testing there is a testing standard which is unique! The Radio Technical Commission on Aeronautics RTCA Standard 160A is an international version of long established DOD standards. Used as a criteria document it could easily be used to form a basis for government recognition of this accreditation by the NSI.

One thing further makes the IEC Quality Assessment System of considerable importance. It is attempting to answer for a segment of U.S. industry and electronic components, the problems arising from private industry needs for quality. From Dr. Leon Podolsky we received the following which explains the nature of this program.

> "1. There has been a de facto laboratory accreditation program in existence in the electronics industry for many years. The telephone company, under the Western Electric Quality Assurance Program for its suppliers, long ago required adequate laboratory facilities and test personnel in its suppliers plants to assure proper test and inspection of the components and materials before shipment. The military departments, beginning very seriously with the Minute Man Missile Program, required their suppliers' to make audits of the components and material suppliers which included approval of their laboratory facilities, etc.
>
> 2. The IECQ System will be the first international quality certification system, and in order to assure equal treatment of suppliers in all countries, it is absolutely mandatory that the test laboratories and procedures of the approved suppliers in each country meet the rigorous requirements of the system and be approved."

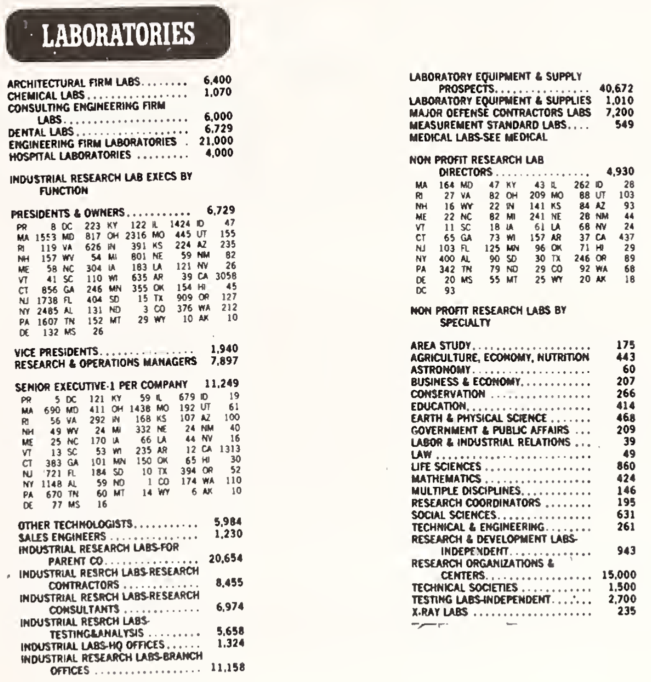
Dr. Podolsky goes on to tell us that "if successful" the IECQ System "will become the example and the norm for certification systems world wide." A cornerstone of which is laboratory accreditation.

NEAR FUTURE ENVIRONMENT

The foregoing discussion attempted to bring to current status some of the important factors in any look at laboratory accreditation. Now it would be well to look at the near future environment for such laboratory accreditation activities.

The name of this era, as we see it, is economics. The public sector's lack of funds, in the form of reducing government budgets will see the move to reliance, where possible, from the private sector. The multiple drains on the private sector will call for a merging and consolidation of programs. Laboratory accreditation is one such program, tied as it is to voluntary standardization and product certification.

Perhaps here it would be well to look at the task ahead for merger and consolidation. Below is a section taken from the Summer/Fall catalog of mailing lists available from the Hugo Dunhill Mailing Lists, Inc., 630 Third Avenue, New York, NY 10017. Under the heading "Laboratories" we find numbers which justify our conclusion that there are more than 50,000 laboratories currently accredited by one or more forms of accreditation, licensure, etc. We have identified over 2,500 firms which conduct testing traditionally subjected to multiple accreditation requirements--to 100 per laboratory in the case of commercial laboratories with extensive high technology nondestructive testing involvements.



LABORATORIES

ARCHITECTURAL FIRM LABS........	6,400
CHEMICAL LABS.................	1,070
CONSULTING ENGINEERING FIRM LABS.....................	6,000
DENTAL LABS...................	6,729
ENGINEERING FIRM LABORATORIES .	21,000
HOSPITAL LABORATORIES	4,000

INDUSTRIAL RESEARCH LAB EXECS BY FUNCTION

PRESIDENTS & OWNERS........... 6,729

PR	8	DC	223	KY	122	IL	1424	ID	47
MA	1553	MD	817	OH	2316	MO	445	UT	155
RI	119	VA	626	IN	391	KS	224	AZ	235
NH	157	WV	54	MI	801	NE	59	NM	82
ME	58	NC	304	IA	183	LA	121	NV	26
VT	41	SC	110	WI	635	AR	39	CA	3058
CT	856	GA	246	MN	355	OK	154	HI	45
NJ	1738	FL	404	SD	15	TX	909	OR	127
NY	2485	AL	131	ND	3	CO	376	WA	212
PA	1607	TN	152	MT	29	WY	10	AK	10
DE	132	MS	26						

VICE PRESIDENTS................	1,940
RESEARCH & OPERATIONS MANAGERS	7,897

SENIOR EXECUTIVE-1 PER COMPANY 11,249

PR	5	DC	121	KY	59	IL	679	ID	19
MA	690	MD	411	OH	1438	MO	192	UT	61
RI	56	VA	292	IN	168	KS	107	AZ	100
NH	49	WV	24	MI	332	NE	24	NM	40
ME	25	NC	170	IA	66	LA	44	NV	16
VT	13	SC	53	WI	235	AR	12	CA	1313
CT	383	GA	101	MN	150	OK	65	HI	30
NJ	721	FL	184	SD	10	TX	394	OR	52
NY	1148	AL	59	ND	1	CO	174	WA	110
PA	670	TN	60	MT	14	WY	6	AK	10
DE	77	MS	16						

OTHER TECHNOLOGISTS...........	5,984
SALES ENGINEERS	1,230
INDUSTRIAL RESEARCH LABS-FOR PARENT CO...............	20,654
INDUSTRIAL RESRCH LABS-RESEARCH CONTRACTORS	8,455
INDUSTRIAL RESRCH LABS-RESEARCH CONSULTANTS	6,974
INDUSTRIAL RESRCH LABS-TESTING&ANALYSIS	5,658
INDUSTRIAL LABS-HQ OFFICES......	1,324
INDUSTRIAL RESEARCH LABS-BRANCH OFFICES	11,158
LABORATORY EQUIPMENT & SUPPLY PROSPECTS................	40,672
LABORATORY EQUIPMENT & SUPPLIES	1,010
MAJOR DEFENSE CONTRACTORS LABS	7,200
MEASUREMENT STANDARD LABS....	549
MEDICAL LABS-SEE MEDICAL	

NON PROFIT RESEARCH LAB DIRECTORS................ 4,930

MA	164	MD	47	KY	43	IL	262	ID	28
RI	27	VA	82	OH	209	MO	88	UT	103
NH	16	WV	22	IN	141	KS	84	AZ	93
ME	22	NC	82	MI	241	NE	28	NM	44
VT	11	SC	18	IA	61	LA	68	NV	24
CT	65	GA	73	WI	157	AR	37	CA	437
NJ	103	FL	125	MN	96	OK	71	HI	29
NY	400	AL	90	SD	30	TX	246	OR	89
PA	342	TN	79	ND	29	CO	92	WA	68
DE	20	MS	55	MT	25	WY	20	AK	18
DC	93								

NON PROFIT RESEARCH LABS BY SPECIALTY

AREA STUDY....................	175
AGRICULTURE, ECONOMY, NUTRITION	443
ASTRONOMY....................	60
BUSINESS & ECONOMY............	207
CONSERVATION	266
EDUCATION.....................	414
EARTH & PHYSICAL SCIENCE	468
GOVERNMENT & PUBLIC AFFAIRS ...	209
LABOR & INDUSTRIAL RELATIONS ...	39
LAW	49
LIFE SCIENCES	860
MATHEMATICS	424
MULTIPLE DISCIPLINES............	146
RESEARCH COORDINATORS	195
SOCIAL SCIENCES................	631
TECHNICAL & ENGINEERING........	261
RESEARCH & DEVELOPMENT LABS-INDEPENDENT..............	943
RESEARCH ORGANIZATIONS & CENTERS..................	15,000
TECHNICAL SOCIETIES	1,500
TESTING LABS-INDEPENDENT.......	2,700
X-RAY LABS	235

Approaches to consolidation will be taken from many points of view. Some will be a tailoring to procurement requirements, some for international purposes, some as currently exemplified by the AALA program, will be the commercial laboratory attempt to mitigate multiple costly reviews. In any event relationships will be made between the market for accreditation and the cost-effective programs which deliver to that market.

One major approach that we are waiting to see is that in the private sector, unaffected by political boundries. Someone will have to explain to us the sanity of the private sector considering U.S. duplication of Canadian laboratory accreditation and the reverse. Another insanity is separate but equal State and local accreditations, of laboratories which operate nationally.

Some piggybacking of accreditation is inevitable. By this we mean that for certain needs laboratory accreditation will be obtained through the extension of an existing program.

However, it is in the area of need to service and meet the needs of international trade where we see direction in the near future for laboratory accreditation. For example the writer has a weekly report which reviews standardization, product certification and similar activities which are affected or influenced by Federal Register published government actions. With the advent of publication in the Commerce Business Daily of information on the GATT treaty partners mandatory standards actions, this information was added to the weekly report. Since many subscribers are trade associations and commercial laboratories we commenced adding CBD notices of procurements by foreign governments.

From the week commencing June 29th of this year through the week ending October 30th we reported procument notices placed by GATT treaty partner governments totaling 483 separate requirements. Most of these notices mentioned forms of pre-bid qualification. These listings were for goods ranging from carpets through computers, from apparel through medical supplies. A form of laboratory accreditation which would allow for U.S. laboratories to become on-sight approval agencies for foreign purchasing is an obviously important area for the future of laboratory accreditation.

To sum up, we know of no laboratory accreditation program on which we have reported, which our on-going monitoring is not feeding back concerns for cost of operation and support. The number of Federal, State and local agencies looking for credible alternatives to current accreditation methods grows, and will continue to grow and accelerate. The number of specific area, expensive to be accredited programs, will peak with the IEEE program and alternatives will be the near future environment for accreditation.

If for no other reason than to support the Quality Products List [QPL] concept employed by public procurement entities the world-over we see economic need for expanded use of laboratory accreditation.

Session 2

INTERNATIONAL TRADE IMPLICATIONS OF LABORATORY ACCREDITATION

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ABSTRACT - The reciprocal acceptance of tests and test data is likely to be the most significant technical issue in future standards-related discussions on trade. The mechanism for dealing with these trade issues is the General Agreement on Tariffs and Trade (GATT)--Agreement on Technical Barriers to Trade, popularly known as the "Standards Code.". In bilateral discussions with government officials of other countries which have signed the code, the Office of the Special Trade Representative encourages foreign governments to recognize the American system of private testing laboratories with our legal system and product liability laws, are far better guarantors of reliability than government agencies. There is a problem however, responding to foreign requests for "official" approval, and there is much interest in the evolving Good Laboratory Practices Program in the OECD and the International laboratory accreditation conferences.

I want to begin my presentation this afternoon by expressing my appreciation to Dr. Stanley Warshaw of the National Bureau of Standards for the opportunity to address this workshop on laboratory accreditation. In my daily handling of trade problems, it has become apparent to me that out of all standards-related practices that require the attention of U.S. Government experts, the reciprocal acceptance of tests and test data comes out near the top. In fact, I believe that it will be the most significant, technical issue in future standards-related discussions. Implicitly this work involves understandings concerning the accreditation of laboratories.

As I read over the agenda for this workshop, I was struck by the number of high level experts who are to gather here today: Baron Whitaker from Underwriters Laboratories (UL) is certainly not a newcomer to this field, nor are Howard Forman, or Howard Kontjes. These gentlemen, along with others from both the public and private sectors, have put many long hours simultaneously protecting public safety and facilitating access to the standards-setting/certification process for foreign and domestic citizens.

My role in this field comes from my connection with the GATT -- General Agreement on Tariffs and Trade -- Agreement on Technical Barriers to Trade, popularly called the "Standards Code." I have been involved, in one way or another, in trade policy for over 6 years now. My first exposure to the Standards Code was in 1977 when I first participated in the Code negotiating group. At that time work had been underway on the Code for some years, under the very capable direction, for the United States' side, of William B. Kelly, Jr. -- currently Deputy Director General of the GATT. Later, Douglas Newkirk, Assistant U.S. Trade Representative for GATT Affairs, whose place on the agenda I am taking today because he had to fly to Geneva at the last moment, took over the negotiations of the standards code. I work directly for Doug, and it is within our office that coordination of implementation of the Standards Code, both domestically and internationally, is handled.

I would like, this morning, to present some of the issues that provide real challenges to the United States in the area of standards-related trade policy. These are challenges to our understanding of the Standards Code as well as to our national federated standards system. In the end, I hope that you will agree that the outlook is good that these challenges can be met, thereby assuring that the Standards Code works to facilitate technical barriers to international trade.

Before going into these challenges, perhaps a few preliminary remarks on the Standards Code would be helpful. While I am sure all of you are intimately familiar with its provisions, it might be useful, perhaps for the benefit of those that have wandered in here to avoid autumn's chill, to briefly outline what the Standards Code does.

The Standards Code covers standards-related activities -- by that I mean the range of standards activities from the development of a standard, through the testing of a product to determine conformity with that standard, to the final certification of that product. Both industrial and agricultural products are covered; however, neither government purchasing specifications nor in-house standards fall under the scope of the Code.

The obligations of the Code involve certain specified procedures that are to be used when a standard or certification system is prepared, adopted, or applied in a signatory country. These procedures include such steps as:

- the basing of proposed standards on appropriate international standards;

- when international standards are not used, proposed standards and certification systems are to be developed under open procedures similar to the "transparent" process currently used in the United States;

- performance criteria, rather than design criteria, are to be used whenever possible;

- participation in relevant international standardizing and certifying activities is encouraged;

- access to national and regional certification systems is to be provided; and

- of importance to this morning's workshop when products are tested, imported products are to be treated in the same manner as domestic products; in addition, the code recognizes that the mutual acceptance of test methods and data can significantly liberalize trade.

The Code also provides for the dissemination of information and technical assistance and has dispute settlement procedures to resolve those issues that cannot be settled through bilateral consultations.

Now on to the challenges.

Implementation

The first major challenge that we face is double-sided, involving the implementation of the Standards Code by the United States and other signatories.

Domestic Implementation is a challenge because we need to be in the strongest position possible to demonstrate internationally that we can and will live up to our obligations. It is a situation where we need to lead by example. Fortunately, for the most part the Standards Code internationalizes already existing U.S. practices. The Code, in effect, ensures that other countries act more like us. As a result, we do not need to radically alter how U.S. bodies -- government and nongovernment -- prepare, adopt, and apply standards and certification systems.

Foreign Implementation provides us with the major challenge in this area. We must keep alert to what the Europeans, Japanese, Canadians, Koreans, Brazilians, Nordics, and other signatories are doing to make sure that they are indeed complying with the provisions of the Standards Code. We have set about doing this in many ways:

- The USTR Office, along with other trade policy U.S. Government agencies, particularly the Departments of Commerce, Agriculture, and State, closely follows foreign implementation. In addition, great importance has been attached to the activities of the Committee on Technical Barriers to Trade, established pursuant to the Code.

- The Foreign Commercial Service in U.S. embassies has been alerted to report on any developments regarding implementation by host countries of the Standards Code.

Regional Standardizing and Certifying Bodies

The second challenge that I see facing the United States in the context of the Standards Code involves the activities of regional standardizing and certifying bodies. As some of you probably know all-too-well, the United States began discussions on the Standards Code more than ten years ago partly because of problems encountered with a European regional certification system. These problems have not entirely gone away despite the entry into force of the Standards Code and the impending initiation of the IEC-Q -- an international certification system for electronic components.

We have problems with the activities of the European Committee for Standardization (CEN) and its electrical counterpart (CENELEC). In the United Statea we believe in either developing national standards or concentrating our efforts on international standardization. It appears that the Europeans have a third allegiance, to European standards. The objective of eliminating technical barriers to trade -- the basic intent of the Standards Code -- is hardly promoted by the adoption of regional standards that favor one group of nations over another.

Broadening of Code Membership

There are currently 32 signatories to the Code, including:

- The European Community and all ten Member States;

- The Nordic countries and those of the European Free Trade Association, including Spain, Austria and Switzerland;

- Canada, New Zealand, and Japan;

- Certain Eastern European countries, such as Hungary, Romania and Yugoslavia; and

- Developing countries, such as Argentina, Brazil, Chile, Hong Kong, Korea, Pakistan, the Philippines, Singapore, and even Tunisia.

We must continue our efforts to encourage more countries to sign the Code, thereby ensuring that its obligations will affect all trading nations.

Effectiveness of Trade Agreements -- the GATT and the Standards Code

Perhaps the most difficult challenge that we face is the most general one. We are now in a position where we can establish the future effectiveness of the GATT, and of the Standards Code. The ground work that we lay now will bear fruit in the years ahead. If we do not concentrate on building a firm basis for the new revised GATT structure and the Standards Code, there is little likelihood that we will be successful in achieving our objective of a responsive mechanism for ensuring that trade problems do not arise, and of resolving them expeditiously when they do. The United States must be vigilant in its insistence that the provisions of the GATT are respected by all contracting parties. In the same way, we must insist that there is faithful adherence to all of the provisions of the Standards Code. We cannot let instances of noncompliance go unchecked. We must meet this challenge with all of the spirit that it requires.

Bilateral Discussions

An important facet of implementation of the Standards Code and our attempts to meet the challenges I have just enumerated, has involved bilateral standards-related discussions with key Standards Code signatories on product specific issues. Inevitably, these discussions come to a discussion on the reciprocal acceptance of test data and on "accreditation" of testing laboratories. For example, we are presently engaged in talks with the government of Japan that aim at having U.S. generated test data recognized in Japan. As a way of facilitating achievement of this goal, we are relying heavily upon the successful development within the Organization for Economic Cooperation and Development (OECD) of "Good Laboratory Practices" (GLP's). Based on GLP's it appears that it will be easier for Japanese regulatory officials to feel assured that U.S. test laboratories comply with traditional Japanese practices.

Yet it is not only in discussions with the Japanese that the issue of accepting test data arises; we are also talking in a similar vane with the French, Germans, and Commission of the European Community. This is a diverse field, without a single coordinating agency for the U.S. Government. As many of you know much better than I, there is no central government testing laboratory in the United States.

We do things differently in the United States than most of our foreign competitors, where government intervention in what we consider to be private sector activities is rampant. Often, foreign governments seek from the U.S. Government some official sanction regarding test data generated by our private sector laboratories. And, we are hard pressed to provide it. Moreover, we are not eager to provide such official guarantee. Part of the reason why our standards system runs so smoothly in the United States is due to the lack of government interference.

There is the problem, however, of responding to such foreign requests for "official" approval. The existence of international GLP's, as could, theoretically, programs such as the Department of Commerce's National Voluntary Laboratory Accreditation Program (NVLAP) -- although NVLAP's limited scope does not cover the product we're talking about.

What we do is, in fact, encourage foreign governments to recognize the American system of private testing laboratories that are "independent" of manufacturers and, therefore, impartial. Furthermore, we point out that our legal system, especially our product liability laws, are far better guarantors of reliability than a government agency could ever be. More often than not, foreign governments are receptive to these arguments, because they know of the fine reputation that American laboratories have obtained over time.

We are also particularly interested in efforts as establishing the framework for "international" accreditation of laboratories. In this regard, I note that the fourth meeting of the International Laboratory Accreditation Conference (ILAC) took place just three weeks ago in Mexico. Surely, ILAC is an important inspiration in the area of laboratory accreditation. However, I believe that we must be vigilant at all times to ensure that ILAC is responsive to American needs. We would have no use for an international system that relied heavily upon official government sanction of testing laboratories, simply because that's not the way we do things in the United States.

In this regard, we have taken steps recently to ensure that U.S. Government involvement in ILAC receives the advice of all agencies that are interested in standards-related trade policy issues. We are, so-to-speak, opening up the process to ensure that whatever evolves out of ILAC meets our trade policy objectives and needs. In this regard, I would like to commend Dr. Warshaw, who has made sure that ILAC is not an exclusive forum for certain U.S. interests.

Truly, this workshop has many important issues to discuss, including the question in your program as to "What, if any, additional measures should be taken to assure that an effective U.S. presence remains in international laboratory accreditation activities, including bilateral arrangements." My Office is certainly interested in the views of those assembled here today and await the outcome of your discussions.

I welcome any questions that you may have.

Session 3

PURPOSE OF LABORATORY ACCREDITATION

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ABSTRACT - Task Force C of the International Laboratory Accreditation Conference (ILAC) has prepared a report which describes a number of needs for laboratory accreditation. Detailed examples illustrating each need are presented. Objectives of laboratory accreditation systems are described. Effects on all segments of the laboratory accreditation community are summarized, as well as effects on international trade.

One of the greatest interests expressed by attendees at the first International Laboratory Accreditation Conference (ILAC), held in 1977, was to have a succinct report of the need for laboratory accreditation, objectives to be served, and the effects and consequences of laboratory accreditation. The task was assigned to Task Force C (originally Task Force 1) under the chairmanship of John Gilmour, Registrar of the Testing Laboratory Registration Council (TELARC) of New Zealand. A draft report was prepared by Mr. Gilmour, reviewed by the members of the task force, further reviewed by delegates to ILAC, and published in final form in the ILAC/80 Proceedings (page 49). This presentation will describe the findings of Task Force C, as adapted to the situation in the United States.

Perspectives on the Need

Perspectives, of course, differ, and a wide variety of perspectives as seen by persons in the United States will be presented in this session of the workshop both by the invited speakers and by members of the audience. To initiate the discussion we thought it would be useful to describe needs, objectives, and consequences as seen by members of Task Force C of ILAC, most of whom are responsible for operating laboratory accreditation systems.

But first a word about the perspective of the chairman of Task Force C, who prepared the initial draft. John Gilmour's original experience in laboratory accreditation came from his work with the National Association of Testing Authorities (NATA) in Australia. Discussions of the need for a way to formally recognize that a laboratory is competent to carry out specific tests or specific types of tests dated back to 1928 in Australia. The need was clearly demonstrated in the early stages of World War II as Australia was called upon to provide defense production to support the war effort. The Approved War Time Test House Scheme was developed and proved quite successful. Established after the war, NATA accredited its first laboratory, the Defense Research Laboratory, on June 30, 1949. TELARC was established in New Zealand in 1973 and Gilmour became its first registrar. Today he is registrar of NATA.

Both NATA and TELARC are managed by councils made up of members of the government and private sector. Both councils were established by Government decisions and Government representatives have a substantial but not controlling interest. A majority of the funding comes from the Government. The task force report reflects some 30 years of operating experience as influenced by persons from the other countries operating more recently developed or newly developing systems.

Need for Laboratory Accreditation in the United States

The need for accrediting laboratories in the United States is clearly demonstrated by the existence of a large group of accreditation systems. Charles Hyer, in his report entitled "Principal Aspects of U.S. Laboratory Accreditation Programs," published on January 24, 1979, described some 56 systems then in operation. He also identified some 50 private organizations which operate laboratory accreditation systems and concluded by stating: "The detailing of private sector programs was not pursued because it was reliably reported from several sources that considering the contractual requirements of National Aeronautics and Space Administration, Nuclear Regulatory Commission, and the Department of Defense, well over 8,000 such programs exist."

The need for laboratory accreditation can be categorized as follows:

1) Private Sector Purchase of Components and Subsystems. This appears to be by far the largest use of laboratory accreditation systems. The driving force is in the military and space purchase of complex systems. Although the U.S. military does not require the use of laboratory accreditation systems, weapon system profits are often linked directly to performance of the systems. Many prime contractors and subcontractors have developed laboratory accreditation systems to test the quality of subsystems and components before the subsystems or components reach the prime contractor for installation into a weapon system. These accreditation systems reduce the amount of testing by the prime contractor and save the logistics costs associated with return of subsystems and components which do not meet the specifications.

2) Private Sector Certification Programs. Trade associations and professional associations provide laboratory accreditation systems to enhance the image of an industry or a profession. For example, the American Kitchen Cabinet Association accredits a number of laboratories for performing certain ANSI test methods on kitchen cabinets. Many such trade associations do not have laboratory accreditation programs but do contract with one laboratory to perform the tests. Some private sector certification programs, such as that of Underwriters Laboratories, rely on their own testing capabilities almost exclusively. Professional associations, such as the College of American Pathologists and the American Industrial Hygiene Association, accredit laboratories to protect or enhance the image of the professionals in those fields.

3) Government Purchase. The Defense establishment, and the General Services Administration in particular, have established Qualified Product Listing (QPL) procedures which require products purchased by the Government to be tested by a laboratory acceptable to the Government. The QPL procedures are a form of product certification designed to qualify products for Government use which meet designated specifications.

4) Government Funding. A number of Government programs provide financial support to the public, where the support is based upon testing by accredited laboratories. One example is the product certification programs at HUD. Another example is in Medicare and Medicaid, where support is dependent upon test data from accredited laboratories.

5) Government Regulation. Some government agencies impose requirements on products before they can be sold in the marketplace. The products must be tested by an approved or accredited laboratory before they can be sold to the public. The Federal Communications Commission program for radio frequency emitting devices and the Coast Guard program on approved safety devices are examples. There are a number of State and local programs in this category related to building codes and the use of safety approved equipment in construction.

6) Government Certification of Products. You have all heard of "U.S. Department of Agriculture--Prime." This certification and others like it are based upon test data from laboratories accredited by the Department of Agriculture.

In summary, then, a variety of needs has led to the development of laboratory accreditation systems:

1) Save money and minimize risk of prime contractors in the sale of systems to the Government.

2) Save money while adding to the degree of assurance that products purchased by the Government are adequate.

3) Save money while adding to the degree of assurance that products purchased by recipients of Federal funds will meet the performance requirements.

4) Add to the assurance of safety for consumer products.

5) Add to the assurance of performance of products certified by the Government.

6) Protect the image of an industry.

7) Protect the image of a profession.

8) Provide laboratory management with internal quality assurance.

In addition, producers of products often seek to identify qualified laboratories for product development, quality control, or failure investigation, or seek recognition for the quality of their own laboratories. Laboratory accreditation serves both of these needs in specialized areas.

With the evolution of a large number of laboratory accreditation systems, there is another need developing: to find ways of consolidating the assessment of laboratories to reduce the cost of accreditation and minimize disruption at the laboratory.

Objectives of Laboratory Accreditation

Laboratory accreditation systems designed to meet particular needs vary in format and substance. Specific objectives which laboratory accreditation systems can include in the attempt to meet the need are to:

1) Ensure validity of test data;

2) Promote the aceptance of test data by users of laboratory services so that test data produced by one laboratory may be accepted at another location without further tests;

3) Facilitate international trade through acceptance of test data from accredited laboratories;

4) Make more efficient use of testing facilities within a country by coordination of existing capability;

5) Add to the credibility of a greater number of laboratories;

6) Give additional status to competent laboratories;

7) Promote good testing practices;

8) Improve testing methods by providing feedback to standards-producing bodies and on the adequacy of the test methods; and

9) Provide technical and other information on accredited laboratories.

Almost all laboratory accreditation systems aim to work with laboratories to provide a consistent level of excellence. Emphasis is on correction of deficiencies rather than on rejection and denial of recognition to the laboratories.

Effect and Consequences of Laboratory Accreditation

Laboratory accreditation is felt by laboratory proprietors and personnel, by the users of laboratory services, and by the community at large. Participation of a laboratory in an accreditation program generates heightened awareness in the laboratory management and personnel of good laboratory practices related to:

1) Calibration of equipment,
2) Documentation of testing methodology,
3) Recording of data,
4) Reporting of test data, and
5) Interlaboratory proficiency testing.

Benefits to the laboratory include a reference for marketing its services, typical upgrading of capability, possible reduced potential for liability, and a basis for assuring its own quality.

Users of accredited laboratories place greater reliance on the data obtained and can often reduce expensive duplicate testing required for audit purposes. Benefits also include more consistent product quality and more willing acceptance of products in commerce.

The community at large benefits from the existence of better and more reliable testing services. The activities of laboratory accreditation organizations have revealed weaknesses in existing testing services and have forced general reappraisals of attitudes relating to the selection and use of laboratories.

These benefits incur costs. Besides the cost of accreditation itself, there may be a cost for increased calibration, a cost for preparing a quality manual and documentation of procedures, and a cost for proficiency tests or standard reference materials. In a well-run laboratory these costs are relatively small because most of the functions mentioned are already implemented and compliance with accreditation requirements is a matter of interpretation or possible changes in format. The costs, when transferred to the manufacturer of a product, can be substantial for laboratories which do only a few of the tests each accreditation period. The cost per test to the user of a high-volume testing laboratory will be very small in most testing areas.

There are benefits to be obtained from using certain types of laboratory accreditation systems in international markets. Most U.S. accreditation systems are designed to provide test data to support the quality or safety of products made available for purchase in the United States. Many foreign products can find acceptance in the United States based on testing done overseas. Little has been done to promote the acceptance of products overseas, based only on U.S. tests. An accreditation system or a number of existing or future systems need to evolve which focus on international reciprocity in the acceptance of test data produced in the country of export. Such agreements would benefit the United States by facilitating foreign trade.

THE NEED FOR A PRACTICAL LABORATORY ACCREDITATION PROGRAM FROM THE PERSPECTIVE OF A SMALL MULTI-DISCIPLINE INDEPENDENT LABORATORY

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ABSTRACT - Most independent analytical laboratories set high professional standards for themselves, not only because of personel integrity, but because such standards are prerequisites to lasting acceptance of our services in the marketplace. Quality assurance systems have been put in place at many laboratories, but these are incomplete until they stand the scrutiny of a qualified outside source. Laboratory accreditation must provide objective and comprehensive evidence of a laboratory's qualifications and capabilities documented by a third party. Lancaster Laboratories supported the original Department of Commerce proposal for a National Voluntary Laboratory Accreditation Program (NVLAP) but that support diminished substantially with publication of the final rule because the program is structured on a product-by-product basis rather than on a class of technology basis. A private sector program, the American Association for Laboratory Accreditation, now exists which can meet our needs, and the NVLAP should be adjusted to one of monitoring and accrediting private sector agencies so as to support our international trading interests. Advantages of accreditation to the laboratories, clients and the public are fully explored.

INTRODUCTION

My name is Earl Hess, and I am the founder, and President of Lancaster Laboratories, Inc. of Lancaster, Pennsylvania. I am also active in a number of organizations in the laboratory and small-business fields. Lancaster Laboratories is a member of the American Council of Independent Laboratories (ACIL); I serve as ACIL's Director of Government Relations and as a member of the Executive Committee of that association. I am a member of the Advisory Council of the Small Business Center of the U.S. Chamber of Commerce. Also, I serve on the Action Council of the largest small business organization in the U.S. -- The National Federation of Independent Businesses (NFIB). I am a member of the Board of Directors of the Lancaster Chamber of Commerce and Industry, Chairman of the Small Business Advocacy Council of the Pennsylvania Chamber of Commerce, and a member of the Advisory Board of the Pennsylvania Technical Assistance Program (PENNTAP). It was my privilege, in 1979, to serve on a special task force of the U.S. Small Business Administration's Office of Advocacy that studied the issue of the Impact of Government Competition on Small Business.

Lancaster Laboratories, Inc. was founded in 1961, and began with a staff of three: myself, my wife and one laboratory technician. During the past two decades, it has experienced steady growth; it presently employs 61 at two facilities, one in Lancaster and the other, our Franklin Division, in Waynesboro, PA. In this, our 20th year, we completed major construction projects at both sites. An entirely new laboratory was built in Waynesboro, and at our headquarters laboratory there was erected a new addition that doubled the size of the facility. Lancaster Laboratories provides services to industrial, agricultural, commercial and governmental clients in the areas of chemical and microbiological analysis, environmental science and technology, and product and process development.

PART I - BACKGROUND AND PERSPECTIVES ON THE NEED FOR LABORATORY ACCREDITATION

I am pleased to have this opportunity to present some of my thoughts about a subject of paramount importance not only to my laboratory and other independent laboratories, but also to the private sector generally and to the consuming public that uses products whose quality assessment has been made in a laboratory. For a system that insures the technical credibility of an analytical laboratory is indeed the "primary standard" on which all product quality measurements are based.

Most of us who operate analytical laboratories as a business set high professional standards for ourselves, not only because of personal integrity, but because such standards are prerequisites to lasting acceptance of our services in the marketplace. Thus, throughout the 20-year history of Lancaster Laboratories, we have been careful in the choice of the highest quality professional staff and have provided them with all possible opportunities for professional growth. We have accepted work only in those areas for which we have the professional competence and the necessary equipment. We are diligent in the regular calibration of equipment, the running of blind reference samples and/or duplicates, and the systematic statistical performance evaluation of each of our scientists and technicians. The basics of our total quality assurance system are, in fact, set forth in our Qualification Manual (first published in 1975), which is freely distributed to our clients, to government agencies, and even to our competitors who flatter us when they borrow from it.

All of these steps are necessary, but they are not enough. Such a program is incomplete until it stands the scrutiny of a qualified outside source. And that's what laboratory accreditation must provide -- objective and comprehensive evidence documented by a third party about a laboratory's qualifications and capabilities.

Thus, at an early stage in our company's development, I sought out such sources to pass judgment on our laboratory's work and to assist in correcting its deficiencies. Until recently, such groups were hard to find; when available, their concern was narrow usually a few specific tests on single commodities. For example, EPA accreditations currently held by our laboratory with respect to the analysis of certain elements in water do not extend whatsoever to the same elements in the more complex matrices such as solid waste and biological specimens. Our experiences with a plethora of such narrow-gauged accreditation programs, none of which even acknowledges the existence of the others, constitute one of the most painful chapters in the history of Lancaster Laboratories. Exemplary of such narrow accreditations, some of which we hold, others of which we do not, simply by reason of economic considerations, are: bacteriological testing of milk (separate programs of PA Department of Agriculture and the U.S. Public Health Service); USDA certification for testing of meat products for moisture, protein, fat and salt; EPA and individual state programs for testing of potable water in five separate areas; testing of peanuts for aflatoxin; USDA certification for testing of poultry products for salmonella.

In listing these it is not my purpose to belittle any of the sponsors of such programs, but to point out the utter impracticality of adequate coverage of my laboratory operation on a product-by-standard basis. For in spite of all these efforts with respect to narrow-gauged accreditation programs, I would judge that 75% of the work we do is not covered by any product-by-standard accreditation program.

As a result of this experience, the need for a broad national program of accreditation by discipline has been clear to me for some time. Anything less is simply inadequate. A system that accredits on a product-by-standard basis is unworkable and impractical for organizations such as ours. The number of individual accreditations for a relatively small, multi-discipline laboratory like Lancaster would be excessive; the cumulative accreditation fees would be prohibitive; and the attendant costs in terms of paperwork, interruptions and lost productivity, would be staggering. My experience is representative of the views of laboratories who are members of ACIL and of hundreds of other small independent laboratories.

Therefore, when the Department of Commerce proposed a program to accredit testing laboratories according to classes of technology in 1975, I and other ACIL representatives reacted with enthusiam. The announcement was made in the Federal Register of May 8, 1975 (Vol. 40, No. 90, pgs. 20092-5), and the program was called the National Voluntary Laboratory Accreditation Program (NVLAP). As I stated in my testimony at a Commerce Department-sponsored public hearing on NVLAP, on June 24, 1975; "I support wholeheartedly the concept of a national laboratory accreditation program and I sincerely hope that from these efforts of the Department of Commerce will emerge such a program that is technically and legally sound and one that will be administered in a manner so as to be honest and fair to all parties concerned."

Unfortunately, when the Department of Commerce published the final rule for the operation of NVLAP, nearly 10 months later, my enthusiastic support diminished. While I was pleased that the Federal Government had recognized an urgent need for a national system to accredit laboratories, whatever their size, I was dismayed to find the following paragraph in the regulations implementing the NVLAP program in a significantly modified form which appeared in the February 25, 1976 Federal Register:

> "A number of substantive changes in the proposed procedures have been made as a result of the public's comments. Some of the more significant changes include a structuring of the program on a product-by-product basis rather than on a class or technology basis. Initially, it was presumed that there existed general and concurrent needs within various classes of technology for the accreditation of laboratories to test all, or many of the various products within each class. On the basis of the comments received, it is believed that this assumption may not be valid. Accordingly, the procedures have been revised to allow the initiation of accreditation services on a product-by-product basis. To counter the potential for establishment of innumerable separate services that might result, the revised procedures will allow the Secretary of Commerce to group similar or related products, as appropriate, when initiating accreditation services."

The more I analyzed the revised NVLAP program, the more convinced I became that its approach was needlessly complex and inefficient and greatly diminished the prospects that my laboratory would be accredited in our major areas of technical competence in a reasonable time and at a reasonable fee. Five years later, I believe my concern has been proven valid. NVLAP still has not initiated or announced plans to start a program for a single one of the multitude of products tested at our laboratories. Nor has it initiated accreditation services for those classes of technology affecting our laboratory.

My deep concern about the role of the Federal Government in laboratory accreditation and the conceptual approach embodied in NVLAP does not blind me to the considerable accomplishments and contributions of the NVLAP program. For one thing, it has created a much better appreciation of the need for and value of accreditation in many sectors. Beyond that, it has developed valuable criteria documents and other procedural materials that have advanced the technical development of laboratory accreditation systems in general. Unfortunately, NVLAP's heightening of public awareness of need without supplying a meaningful and manageable program created the awkward position of having to explain the lack of accreditation when there is no accreditation program available for a particular area.

In 1978, an alternative to the NVLAP program appeared in the private sector --the American Association for Laboratory Accreditation (AALA). The establishment of a private sector program designed to accredit laboratories by classes of technology was strongly supported by independent multi-disciplinary laboratories like ours. AALA has been structured as an organization in a very sound manner; its committees have developed standards documents and specific guidelines for laboratory inspection in several disciplines; it has selected and trained inspectors; and more than a year ago it began accrediting laboratories in the chemical discipline. Our laboratory at Lancaster was the first laboratory to be inspected and accredited by AALA. This event was significant for Lancaster Laboratories. For we had indeed realized our long-time desire to be examined in a comprehensive and thorough manner by a qualified, disinterested third party. Completely apart from any national recognition that AALA accreditation may yield, the constructive critique of our operation by the AALA evaluators was worth the entire cost and effort involved in accreditation.

The progress of AALA came at a time when I and many other independent laboratory owners were coming to a second conclusion about the structure of an effective national program of laboratory accreditation. Not only must it accredit by discipline rather than product; it must also be based in the private sector. Several developments in the past two years led me to concur in this conclusion.

In 1979, I served on a task force convened by the Office of Advocacy of the U.S. Small Business Administration to study the subject of Government competition with small business. The task force collected testimony from representatives of a wide variety of businesses and from all parts of the country. We were amazed to discover the huge proportions of the Government competition problem. The following are but some of the business sectors where it was found to exist: audio-visual products and services, automated data processing, printing, office services, research and development, testing, manufacturing, systems engineering, security, food services, laundry and dry cleaning, health services and transportation. In all these areas, the taxpaying private-sector finds itself in direct competition with agencies of the Government.

The culmination of the task force's work was the publication in March, 1980, of a report: "Government Competition: A Threat To Small Business." Although there is no mention of laboratory accreditation in the report, the implications for the topic of this workshop are clear. The single most important recommendation of the task force report is that the Federal Government and the Congress should take actions to emphasize and make more effective a policy that has been on the books for years, that is, that the Government should rely on the private sector for goods and services wherever practical. The report recalls that:

> "As early as 1952, President Eisenhower cogently stated in broad terms the basic principles concerning Government reliance on the competitive private sector for goods and services needed by the Government:
>
> > To bring government closer to the people we will set up these principles and adhere to them; That no Federal project, large or small, will be undertaken which the people can effectively do or be helped to do for themselves; that no Federal project will be undertaken which private enterprise can effectively undertake; that no project and no program will be started on the Federal level which can be undertaken and effectively carried through on the State and local level..... (Study Group Report, p VII 44.)
>
> The President's test was both simple and broad--the ability of the people to perform the function themselves."

OMB Circular A-76, an official Government statement of this policy of preference for the private sector, has been in effect for 25 years, but its application has been sporadic. Happily, the Reagan Administration has affirmed its intention to implement a strong policy of reliance on the private sector. The Administration's support for A-76 was stated in no uncertain terms less than a month ago in testimony, on October 28, before a hearing of the Joint Economic Committee on The Impact of Government Competition with Small Business, in the following words:

> "The Reagan Administration strongly supports the general policy of reliance on competitive private enterprise, and has vigorously embraced it as evidenced by the following actions:
>
> - The President affirmed his support of this program in the March 1982 budget revision which stated "It is the general policy of the Administration to rely, whenever possible, on the competitive private sector...OFPP is, therefore, working with agencies to...increase agency compliance with OMB Circular No. A-76.
> - A memorandum and a series of letters were sent to all executive agencies and departments in April 1981 reaffirming the policy and requiring it be vigorously implemented;
> - An OMB bulletin was sent to all executive agencies and departments requiring them to submit detailed information on their implementation of the program and its impact on their future budget submission; and
> - In June of this year, Circular No. A-11 was revised further to strengthen linkages between budget submissions and agencies' overall implementation of Circular No. A-76.
>
> "We would welcome a clear statement of intent of the Congress in support of the policy that the Government should not compete with the private sector. The A-76 policy has been applied unevenly over several administrations, and it is now time to make it work. We believe that proposed Senate Joint Resolution 93, introduced by Senator Hayakawa on June 22, 1981, is an excellent means to clarify and reaffirm this as a national policy. It will illustrate to the public and private sectors alike that it is truly the Government's policy to rely on the private sector for functions that are not inherently governmental."

Laboratory accreditation is not inherently governmental, any more than is its allied activity, standards development. As a matter of fact, in standards development we have a good model for what should happen in the laboratory accreditation field. In the past few years a consensus has developed about the proper roles for Government and the private sector with regard to standards. That consensus was well expressed by Dr. Howard I. Forman, recently retired Deputy Assistant Secretary of Commerce for Product Standards Policy, in an address at the 17th Annual Symposium on Trade Association Law and Practice of the Antitrust Committee of the Bar Association of the District of Columbia, on February 25 of this year. My quote from Dr. Forman's talk is lengthy, because the example of standards development is so instructive for our purposes:

> "The relative merits of encouraging voluntary development of standards by non-government sources, and the need to have the government exercise some measure of oversight of the standards development process for reasons such as are represented by the plywood and gas vent damper cases were carefully weighed in a two-year study by the Interagency Committee on Standards Policy (ICSP), which has been chartered by the Secretary of Commerce and which it has been my privilege to chair over the past five years. In July 1976 the ICSP promulgated a set of nine policy principles for standards development, one of which was that the Federal Government should use standards developed by private sector standards-setting bodies wherever and whenever possible. (It was these principles that later were to become the basis for a government-wide policy directive issued by the Office of Management and Budget, known as OMB Circular A-119, of which more will be said later.)

> "The logic of such a posture is inescapable. The many hundreds of committees which write standards, each of which over a period of two or more years meet many times to set product standards and related matters, involve highly trained scientists, engineers, and the like, mostly of wide experience and heavy responsibilities in their normal professional pursuits. The time they give to this voluntary, unpaid service, together with their expenses for travel and lodging annually amounts in the aggregate to many millions of dollars. Much of the varied expertise required for those committees exists in the private sector, and the employers of most of those experts foot the bill to support their participation in standards-writing activities. Under such circumstances, what government administrator would want to upset such a nice situation, and more or less take over the job that the private sector is doing in providing the standards that industry and governmment urgently need?
>
> "It seems to me that the government's proper role should be in assuring that enough standards are developed which will meet the needs of both the government and the private sector, and that they are good standards in all respects. The government's concern should be that the standards should help make possible the recognition of good products, that the standards should be non-restrictive and should not limit competition illegally or unreasonably, and that they should be developed in timely fashion to meet all reasonable needs. If the private sector can supply those needs, both of government and industry, and if the standards developed by the private sector are not used to perpetuate production of products which are unsafe, unhealthy or which might contribute to the consumer's ignorance concerning those products, why shouldn't the private sector be encouraged to fill those needs? Especially if the government could reserve the right to develop needed standards on its own in case the private sector failed to meet a particular governmental need, in which case the government literally would have, as the saying goes, 'the best of both worlds. . . .' I've been suggesting that it is highly desirable to have the government, in essence, get out of the standards developing business and leave the work and responsibility for providing standards the country needs to (qualified) private sector organizations."

The principles governing the Federal/private-sector relationship in standards development apply equally to laboratory accreditation. Accordingly, the American Council of Independent Laboratories recommended earlier this year that the NVLAP program be drastically altered to recognize private-sector organizations who carry out the actual accreditation of laboratories. In his May 5 letter to Dr. Forman, on behalf of ACIL, Mr. Roger Amorosi stated the ACIL position in these words: "We believe that the goal of NVLAP and the private-sector organizations interested in accreditation should be to transform NVLAP from an agency accrediting individual laboratories to an accreditor of private-sector accrediting organizations. Strong precedents for this kind of Federal role exist in other fields such as education. In this spirit, ACIL has been clear in expressing its view that NVLAP should be phased out as it now exists. The NVLAP staff can and should play an important role in participating in a transition to this new approach and ultimately serving as the accreditor of private accrediting organizations. In turn, the private sector should continue to work hard to assure that there are broad capabilities in the private sector to discharge the need to accredit laboratories of all kinds."

If this proposal is adopted, NVLAP's role will be adjusted to monitor and accredit private-sector accrediting agencies, and serve as the lead Government agency in the international arena on matters of laboratory accreditation. This role is an essential U.S. Government responsibility if the United States is to pursue its international trade interests effectively as a result of the adoption of GATT and the development of the International Conference on Laboratory Accreditation (ILAC). To be credible to our trading partners, the Government itself must represent the U.S. interests in laboratory accreditation and recognize private accreditation systems. While I have described AALA as one private-sector accrediting system which is conceptually sound and logical, it should be noted that other significant private-sector accreditation programs exist and I have no strong views about how these private systems should evolve in the future except that they be discipline rather than product oriented -- what I believe is fundamentally necessary is that Government rely on the private sector to perform the accreditation function and assist interested organizations in every possible way.

The success of this eminently sensible proposal hinges on a spirit of true cooperation between Government and the private sector. I speak for many independent laboratories in stating that we look to the Department of Commerce for leadership in encouraging cooperative efforts during this workshop and in the months that follow to move to reliance on private-sector organizations for performance of the accreditation function. My hope and that of my colleagues in the laboratory community is that this workshop will mark the beginning of a cooperative effort and one where the Department takes strong action to implement this modified approach.

PART II - ADVANTAGES OF LABORATORY ACCREDITATION

I would like now to describe some major advantages of laboratory accreditation by discipline -- to laboratories themselves, to clients of laboratory services, and to the public.

Advantages to Laboratories

Earlier in this statement allusion was made to the heavy burden that independent laboratories have been carrying in the absence of an efficient, discipline-based, comprehensive national system for accreditation of laboratories. Many of these laboratories are small businesses, which, by definition, are least able to bear governmental and regulatory burdens. The files of Lancaster Laboratories are filled with specific examples of this burden, examples that, unfortunately, are typical of the situation throughout the laboratory community. Time does not allow the detailed listing and description of many specific cases. I will, therefore, illustrate this point with one recent and typical example.

The administration of the Clean Water Act was properly assigned to EPA which in turn provided states with the option of either seeking primacy and administering their own programs within broad Federal guidelines or of simply having the Federal government administer the program directly. Laboratory accreditation is a significant part of that total program. Most states sought and obtained primacy and consequently developed their own laboratory accreditation programs. These state programs are similar in some respects, but sufficiently different in others so that in many cases reciprocity is not granted. Thus, for example, if a laboratory certified in New Jersey wished to perform water tests for a local firm which also has a plant in Michigan, it is likely that a separate Michigan accreditation would have to be obtained. Pennsylvania chose not to seek primacy so that we had the opportunity to obtain Federal (EPA) accreditation. We assumed that such accreditation would be generally accepted. But not so! When we tried to market our laboratory services in Maryland from our EPA-accredited Waynesboro laboratory (which is essentially on the Pennsylvania-Maryland border), we were told that Maryland would not accept our EPA certification and in fact that Maryland was not accrediting independent laboratories! Thus for the past couple of years our branch laboratory there (accredited by EPA in its own right) is denied half of its market by this rigid and fragmented system. I am aware of one small Maryland laboratory which specialized in water testing that went out of business, primarily because of the unavailability of accreditation in the state of Maryland.

Recently, we received an RFP issued by USDA for regional water testing services. This was in direct response to President Reagan's insistence on the strong implementation of OMB Circular A-76. In order to qualify as a bidder, our laboratory would have had to obtain in addition to its EPA accreditation, individual accreditations in each of the states from which samples would have been submitted (about 10). We had no idea how much red tape and cost this would involve and had insufficient time to find out. Therefore, we were forced to bid the job at a price which reflected this set of requirements. It came as no surprise that another firm -- perhaps better informed, or perhaps unaware of the regulatory complexities -- was the low bidder.

From the preceding, it should be easy to appreciate the paramount benefit to laboratories from a practical, private-sector accreditation program on which Government, industry and the public can rely. Such a program spells relief for me and my colleagues, a savings of millions of man-hours and more millions of dollars currently eaten up by the fees and paperwork of duplicative accreditations. Our accreditation by AALA has already begun to bear fruit in this regard. There is seldom a week goes by that industry or government agency representatives do not visit our laboratory to review our adherence to Good laboratory practices or in some way to make an assessment of our operation - in other words, to conduct a sort of mini-accreditation. Since having been accredited by AALA, we describe the AALA program for these visitors and review the quality-assurance steps dictated by it. They invariably leave with a sense of appreciation for the reasonableness of the system.

In the recent past we underwent a periodic laboratory inspection by FDA, by reason of the quality control analyses we perform for several small drug manufacturers. This most recent inspection was completed in two hours, whereas in the past, they have gone for one to two days. I'm convinced that our AALA accreditation was the large part of the reason for this substantial time reduction.

A second benefit to the hundreds of competent small independent laboratories in the U.S. is the opportunity to achieve true "national recognition." Presently, this kind of recognition is the prerogative primarily of large, well-established laboratories which through the years have acquired a name in industrial and Governmental circles. Newer firms, and especially smaller new companies, face formidable odds in gaining recognition. The economy would benefit from a system which recognizes and better utilizes the capabilities of hundreds of such firms.

There is no denial that a national reputation does not develop automatically but rather derives from professional competence over time. Very candidly, I can say that our own laboratory has acquired a hard-earned recognition in several areas and my marketing manager would shoot me if I tried to conceal it. But I would warn that national recognition acquired over the past twenty years is no more of a guarantee that my laboratory continues to operate at a high professional level than was the performance of U.S. auto manufacturers in the 1950's and 1960's a guarantee that their stock would continue to be a blue-chip investment in succeeding decades.

Therefore, in the matter of recognition, laboratory accreditation will serve two ends: (1) it will assure that laboratories which have acquired national recognition by prescription, as it were, continue to merit that distinction; and (2) it will enable qualified newcomers to the field to prove themselves in a fair and objective forum, and having earned their credentials, to compete on an equitable basis with their equally qualified elders.

A third advantage to the testing laboratory derives from the accreditation process itself. In the course of the on-site laboratory evaluation by inspectors of the accrediting agency, strengths and weaknesses of the laboratory operation are highlighted. This activity invariably will lead to refinements and improvements. In our own case, Lancaster Laboratories was visited by AALA inspectors in August, 1980, prior to receiving AALA accreditation. As a result of the AALA inspection, improvements in our operation were made in the areas of record keeping related to instrument calibration and maintenance, in our safety program, and in improved housekeeping operations.

Advantages to Clients

Clients of laboratory services, of course, will also find great advantage from a credible and efficient national program of laboratory accreditation. In the first place, accreditation provides a would-be client with assurance that the laboratory with which he is about to contract has satisfactorily demonstrated its technical competence to a qualified third party. In the absence of accreditation, officials of manufacturing firms, Government agencies, architectural and engineering firms, and many other users of laboratory services call organizations like the American Council of Independent Laboratories each week, trying to locate laboratories qualified to do various kinds of testing. In the future, individuals seeking such verification will merely have to obtain the list of laboratories accredited in the appropriate discipline.

In some cases, the desire for assurance of competence has led some large manufacturers to set up their own accreditation programs. Before contracting with any laboratory, company inspectors are sent to examine the facility to be sure the laboratory is capable of doing the job properly. When such clients accept accreditation by a national agency as valid and adequate, they will save considerable amounts of time and money now expended on in-house accreditation programs.

Finally, a viable national accreditation system will create more competition in markets where the "national recognition" discussed earlier is practically a sine qua non for the testing laboratories. One such market is that of life safety products, where a few large certifiers dominate. Manufacturers of these products, especially smaller manufacturers, suffer from this lack of competition among certifiers. Accreditation will afford these clients more choices and lower costs.

Advantages to Public

In a real sense, the bottom line on laboratory accreditation, as on most other programs, is the public good. Unequivocally, it can be stated that the public will be well served by a technically sound, discipline-oriented national system of laboratory accreditation that is carried out in the private sector. I will cite only some of the more obvious advantages to the public.

As the end users of the products, commodities and services tested in our nation's laboratories, the public has a right to expect that these tests are carried out conscientiously and competently, that they are consistently productive of accurate data, and that they result in safe and reliable products. Accreditation is a most important means for protecting this right.

Further, accreditation should mean that the public can purchase these better products at lower costs. As was indicated above, accreditation will produce savings for the laboratories and the manufacturers; at least a portion of these savings should be passed on to the consumer.

Accreditation will enhance international commerce and have a beneficial impact on the balance of trade.

The public will also get a better return on its tax dollars if the accreditation is handled by a private-sector organization rather than a Government agency. The premise of this claim is the well-established truth that the private sector is generally more efficient than governmental entities. Early this year, James Bennett and Manuel Johnson published a valuable treatise on this subject, entitled "Better Government At Half The Price: Private Production of Public Service." The following is a brief passage from the Bennett-Johnson study.

> "There have been many investigations into the relative efficiency of the private vis-a-vis the public sector in providing such services as refuse collection, fire protection, debt collection, health care and hospitals, ship repair, electric utilities, and airline services. Less comprehensive, but useful studies have also been made of weather forecasting, policing services, ambulance service and education. Some of these activities are, or have been, regulated by government, including airlines, utilities, and hospitals. Moreover, health facilities are also often regulated through the accreditation process by private associations. Regulation, especially that which guarantees a specific level of profits, reduces the incentives for cutting costs and may also inhibit a company from achieving an efficient scale of operations. For example, airline routes were previously allocated and utilities are required to provide service to all users in their service area. Yet the private sector, despite such restrictions, has been found so consistently more efficient that economist Thomas Borcherding has suggested the 'Bureaucratic Rule of Two: Removal of an activity from the private to the public sector will double its unit costs of production.' The Bureaucratic Rule of Two holds that the taxpayers can have the same services at half the cost. This is a very important conclusion, especially when it is realized that some of the studies did not even take into account all of the costs of government provision of goods and services. If these costs had been taken into account, transferring public services to the private sector would show even greater savings to the taxpayer."

CONCLUSION

In conclusion, let me reiterate the major points of this paper:

1. The only national laboratory accreditation system that is both practical and efficient is accreditation by discipline.

2. Laboratory accreditation is not an inherently governmental function. It belongs in the private sector and will be conducted there much more effectively and economically.

3. For the above reasons, the Commerce Department's NVLAP Program should be altered. NVLAP should gradually withdraw from the actual accreditation of laboratories and become the accreditor of private-sector accrediting systems and the United States' international liaison in the area of laboratory accreditation.

4. The kind of accreditation program we recommend will have great advantages for the general public, the users of laboratory services and laboratories themselves.

Thank you for this opportunity to present my views.

INDEPENDENT LABORATORY
WITH MANY
SEPARATE LABORATORY LOCATIONS

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Abstract: Several hundred corporations exist which operate from executive office/laboratory facilities with branch laboratories at other locations. Approval of the Corporate Standard Quality System implemented at all facilities would save paperwork, time and cost to both the laboratory and accreditors. Systems to be addressed in the Master Quality Program are listed. Management procedures for control of the system throughout the corporation are described. Similiarities, differences, advantages and disadvantages between corporate control and individual site accreditation are discussed. Several concerns are expressed about present and proposed accreditation procedures.

There are many testing agencies in the United States with facilities operating as branches or districts under the control of an executive office and main laboratory. Thirty years ago there were only three or four. Today there are probably several hundred multi-laboratory corporations.

This type of organization developed to take advantage of the economics of scale, interchange of personnel and equipment, and the ability to serve any client in a uniform manner throughout a geographic region or the entire nation.

Several concerns come to mind when considering a requirement for separate applications, fees, reviews, on-site examinations and related reports for each branch laboratory. Individual site accreditation will create an excessive amount of redundant paperwork and take an inordinate amount of time for review and approval. Both of these will add significant costs to both the laboratory and accreditor.

The laboratory with branches performing similar types of services seeking accreditation must, first and foremost, have a master Corporate Standard Quality Systems Program. The quality system has to be a part of operating policy and be implemented in all facilities in a uniform manner.

The primary document would be the Quality Assurance Manual which details organizational structure, the reasons for the existence of the system, and generally what parts of the laboratory operations must be controlled. Specifically, points to be addressed must include

1) Organization, duties and responsibilities
2) QA program controls
3) Procurement control
4) Document control
5) Sample control
6) Test procedures and instructions
7) Calibration and control of equipment
8) Personnel qualifications
9) Non-conformance and complaint handling
10) Audits, internal and external

Those of you familiar with the nuclear energy industry will recognize these parts to be the essential elements of the eighteen criteria in 10CFR21, Appendix B. I do not mean to infer that the programs we are discussing be as detailed and stringent as those required in the nuclear program, but most elements can easily be incorporated into a commercial system.

The program is controlled by the Quality Assurance Department in the executive offices. The Q.A. manager reports directly to executive management and has a staff of eight. Duties include program writing and revisions, systems operations reviews, maintenance of corporate calibration standards, calibration of certain equipment and internal audits.

Quality control procedures have been implemented which describe, in detail, how each part of the Q.A. program is to function.

Procurement control, for example, defines the procedure for ordering of specified equipment and supplies, including receiving inspection requirements before placing the purchased materials into service.

Personnel qualification procedures include requirements for experience, training, examination and certification for various types and levels of technical employees. Standard written and practical examinations are employed, certification file documents defined, and re-examination/certification times established. Eye examinations, including color perception, are required for the type of test or inspection being conducted.

Equipment calibration procedures cover all measuring and weighing devices. Calibration frequencies, methods, accuracies and documentation requirements are specified. Where equipment requirements are specified in national standards, these are included as a minimum. Where standards do not include specific details for equipment, corporate standards have been established. If equipment is suspect, damaged or found to be out of calibration, procedures define "out-of-service" status, recalibrating , repair or replacement requirements.

In addition to continuous desk audits, the system requires an in-depth audit by the Q.A. department staff made at least once each twelve months. A sampling of all parts of the system is made from a detailed check list and a report issued. If deficiencies are found, corrective action must be taken and a written response produced within 30 days.

Executive management is required to perform spot audits during regular visits which occur two to four times per year. These would specifically include verification of corrective actions taken in response to previous Q.A. audits. Observations of tests in process would also be made. If deficiencies are noted, they are discussed with the local management and reported to Q.A.

If analysis of the system operation reveals procedure or equipment deficiencies, Q.C. procedures are revised or alert bulletins are issued to responsible management. This might include more frequent calibration, or even replacement of equipment. In some cases, equipment from certain manufacturers has been "blacklisted" because of an inability or unwillingness to meet ASTM standards.

Probably the most important control is the unhappy client with a complaint who refuses to pay his bill. All complaints are reported to management and investigated. If a quality system breakdown has occurred, necessary corrections are made. The market place control, "bad work means no work." is a considerable incentive.

Corporate control and separate site accreditation systems are similar in that they both require the implementation of a quality system covering all aspects of the work effort. Equipment calibration, personnel qualification and test controls are required in each system. Each require on-site reviews.

The two systems differ in that the corporate program control is ongoing and continuous while an accreditation system might only get a cursory review only once every one to three years. In addition, the corporation audit (assessment) system is conducted by personnel who are thoroughly familiar with the corporation's testing business and the requirements of it's clients. External assessors are more often than not completely unfamiliar with laboratory testing realities.

Theoretically, the acceptance of a universal accreditation system would cause all laboratories to function at the same level of technical competence. Recognizing the real world of competition, this might be a utopian view.

Many of those involved in the attempt to develop a satisfactory accreditation system have hoped that it would replace the multitude of public and private accreditation and approval programs now in existence. The only way this could happen would be if the accreditation system was flawless, satisfied everyone's needs and desires, and was made mandatory through law. Once again, this might be utopian thinking.

It is difficult to state that there are disadvantages to an accreditation system. To say that accreditation is bad would be comparable to speaking against God, mother and country. The cost of accreditation to the small, two technician laboratory, for accreditation and program maintenance might be prohibitive. In the real business world, providing quality services at a competitive fee means survival with a profit.

Certain aspects of accreditation procedures should be of concern.

1) The "single material" versus "discipline" accreditation approach has been debated for years, and will be by others at this meeting. The cost, time and paperwork necessary to become accredited for each individual material used in construction, for example, will be intolerable.
2) The capability of the assessor will be critical. They must be well trained and thoroughly knowledgeable in the laboratory science being assessed. Above all, they must be able to maintain impartial judgement.
3) The accrediting agency should set basic requirements for the various parts of a quality system. The laboratory must have the freedom to establish specific methods, tailored to the corporation's needs, required to assure accurate test results.
4) The accrediting agency must recognize the fact that certain national standards contain test requirements that are impossible, or impractical to meet. Will the accreditor recognize this in granting the approval? Keeping in mind our litigious society, where does the liability lie when an accreditation is given for testing or analysis in full accordance with a standard which cannot be met?

In conclusion, accreditation can be good for the laboratory industry only if properly designed and administered. If a corporation with branch facilities has a standard quality system in effect in all locations, the accreditor might consider blanket approval of the system, and possibly eliminate the necessity for individual facility on-site visits.

WHY CONCRETE LABORATORY ACCREDITATION -- WHY NVLAP

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ABSTRACT - Ready mixed concrete producers (manufacturers) support the need for laboratory accreditation. In commercial concrete construction acceptance testing is performed by commercial laboratories, but there are no objective standards for the quality assurance and quality control of these laboratories. The operations are small and highly competitive. Too often improper testing procedures and errors result in low strength test results which must be investigated to determine if remedial action is needed in the structure. These delays disrupt the construction process. Accreditation also provides a standard by which the concrete producers own laboratory staff can be measured and thereby gain recognition that is denied them in the absence of an objective detailed standard for performance.

I am concerned over the AALA-ACIL proposals that NVLAP relinquish its current accreditation role. I wonder if AALA can generate the technical resources necessary to do the job and whether there is a real commitment to the E 548 generic criteria. Further the AALA private industry appeal seems a diversion when they are themselves proposing federal funding.

Introduction

The ready mixed concrete producers manufacture concrete and are responsible for the quality of the material delivered to the job site. Concrete is a unique material in that it cannot be tested before the material is actually used in a structure. Although there is a valid testing methodology, the concrete construction industry is much fragmented and few concrete laboratories have well organized quality control - quality assurance programs. There is a need to identify well organized professional laboratories and improve the quality of testing services available. Also I am concerned over the proposal that AALA replace NVLAP as the laboratory accreditation body.

Accreditation of Concrete Testing Laboratories

Concrete testing is in many ways unique. The acceptance tests are performed on job sites often under trying conditions in circumstances where supervision is difficult to achieve. In typical commercial building construction there are a whole list of interacting parties.

1. The public building code authority considers public safety. They require submission of concrete strength test results.
2. The building owner employs an architect or engineer to prepare plans or specifications.
3. A general contractor hires subcontractors.
4. The concrete manufacturer rarely has a contract with an owner but furnishes material to a contractor.
5. The contractor generally hires the lab.

Since testing is often a bid item the contractor often selects the lowest bid or even decides to make the cylinders with his own labor and deliver them to the laboratory for testing. About half of all cylinders are contractor made. Since the required capital investment for concrete testing is modest and no high level of scientific knowledge is required there are lots of backyard garage and basement labs in the industry.

For many years, ASTM has produced test methods for testing concrete -- C 31, C 39, C 143, C 231, etc. The concrete manufacturers and others have refined the methods. In an attempt to remedy problems the refinements have produced requirements in the methods that are impracticable if not impossible to achieve in typical circumstances. In the mid 1960's ASTM formed a blue ribbon Board of Directors Committee to prepare a standard for construction materials laboratories. The result was ASTM E 329-67T. Testing laboratories and others have been very proud of E 329 when, in fact, it didn't do anything very important. Basically the requirements of E 329 are:

1. A brief section on the responsibility of an inspection and testing agency.
2. Required inspection of equipment and facilities every 3 years by the CCRL.
3. Required a registered engineer with 5 years experience in management; and supervising laboratory and field technicians with 5 years experience.
4. Required concrete laboratories to have a complete list of equipment for some 23 different test methods regardless of whether the lab ever performed the test.

The really significant development was the establishment of ASTM Committee E 36 and ultimately E 548, Generic Criteria for use in the Evaluation of Testing and/or Inspecting Agencies. This method provided generic criteria for evaluating the following characteristics of a testing agency:

1. the organization
2. the human resources
3. the material resources
4. and the quality systems (quality assurance and quality control).

The NVLAP process uses general and specific criteria that incorporate the substance of E 548 and apply it to specific products or groups of test methods. This accreditation provides, for the first time in concrete testing, a way be which a user of laboratory services can identify and specify the quality of the service desired or expected.

In concrete testing the incidence of low strength tests from testing errors and mistakes in procedures is extremely high. Perhaps a third of all low tests requiring further investigation are due to improper testing and not to deficiencies in the quality of the concrete.

An example of some of the difficulties that are encountered is given in Tables 1 and 2. Table 1 summarized tests on Job 1 by laboratory A on two classes of concrete. In both, strengths are low enough to require investigation. Table 2 provides a comparison of results between Lab A and the concrete producer's Lab B. Cylinders were made from the same well mixed sample of concrete by each lab. Tests were made on two jobs with each of two classes of concrete.

Laboratory A produced results that were almost 700 psi less than Lab B for all classes. Further, the standard deviation of the difference is quite large.

Since the comparison tests were not complete the engineers decided to drill 60 cores. The core strengths met acceptable standards suggesting that the cylinder tests were probably in error. In testing, short of intentional fraud, there are very few things that will increase strength above that obtained on "standard cylinders." Therefore, with some caution, it is generally possible to assume that the lab with the higher result is using the correct procedure.

Table 3 is a summary of comparisons between 15 pairs of laboratories in different parts of the country. In each instance, both labs made and tested cylinders from the same sample of concrete. A total of 6 to 10 samples were tested by each lab pair.

The data demonstrate that the agreement between laboratories varies greatly. Differences between laboratories often exceed 200 psi and from the standard deviation it is clear that in any single comparison the results migh differ by at least 400 psi. This type of comparison is one of the proficiency testing program required in the concrete LAP.

In summary, the concrete producers support accreditation for two principal reasons. First, too often current practices and competitive conditions produce an unacceptably low standard of testing quality. Accreditation provides a method for evaluating the capability of the concrete producers quality control and testing organization. In the U.S., concrete producers do not undertake the formal acceptance testing of their own product.

Should AALA Replace NVLAP?

I have been following the AALA-ACIL proposals with considerable interest and will be very much interested in the other sections of this workshop.

The various spokesmen for ACIL and AALA including Roger Amorosi and Lars Rossi in various position papers and letters have made several important points.

A. That NVLAP accredits by-product by standard and that AALA, like NATA in Australia, will do it by discipline and sub-discipline.
B. That commercial labs will desire accreditation in a wide variety of methods and products and that the NVLAP documents will be too detailed and require too much paper work.
C. That government (NVLAP) shouldn't do anything that private industry can do.

The overall concern I have is that the laboratory community ACIL represents would like a simple inspection by peers without detailed specific criteria that can be documented. Perhaps this is why there is so much enthusiasm for ASTM E 329.

I was reassured by Roger Amorosi's(1) statement that AALA "intends to use it (E 548) for every discipline." The real issue is the extent and detail AALA would employ. Would they require proficiency testing for concrete compressive strength test? AALA should note that in the concrete LAP the compressive strength test was considered the critical method and two proficiency testing programs were included. No proficiency testing was considered necessary for slump, unit weight and air content tests.

NVLAP has been criticized for being too detailed and requiring too much paper work. Even some of those on the NVLAP staff seem to have missed the obvious difference between the concrete and thermal insulation LAPs. In thermal insulation a lab selects the methods it performs and is inspected for those it performs. In concrete only a few of a whole book of test methods were listed. These methods were those of greatest commercial importance. In the future, other concrete test methods will be added, but I would hope that it would not be necessary to include methods which are based on similar technology and procedures.

A central issue between accreditation by NVLAP and AALA may be whether the organization and procedures for developing accreditation criteria will be open and accessible to all parties. The accreditation decision appears to be reserved to a board of balanced composition. It does not appear that AALA has available a procedure which permits comment by the general public and requires consideration of that comment.

Another charge made by AALA is that government should not do what can be done better in private industry. It is a popular appeal, but I wonder if AALA can collect the resources necessary to develop the system needed without compromising the quality of the product.

The AALA membership fees are significant and will inhibit participation by many individual companies and organizations.

The NATA system, AALA favors, relies on the Australian government for 60 to 70 percent of its funding.

NVLAP was designed to be self-supporting, and it is clear that it will be sometime before that can be achieved. In the concrete LAP it is clear that the benefits of accreditation will greatly exceed the modest expenditures by the federal government.

The final point is a question of whether AALA will be able to defend a fair but tough accreditation system against a legal challenge from a determined laboratory deprived accreditation. I suppose it might be said that NVLAP can be attacked through the political process and that AALA may be susceptible to the legal threat.

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(1) November 1980 ASTM Standardization News, p. 21-24, "All about AALA."

These are some of my concerns. I am confident that NVLAP is accessible and can change, improve and evolve. Perhaps there is room for both NVLAP and AALA in their presently conceived roles.

Table 1. Results of Strength Tests on Job 1 by Laboratory A.

28 day strength tests made by the commercial laboratory of record on Job 1.

Class, f'c	No. Tests	Avg. Str.	Std. Dev.	Tests Below f'c No.	Tests Below f'c Range
3000	24	3360	500	5	2300-2900
5000	14	4820	300	8	4350-4900

Table 2. Comparison of Results by Labs A and B Cylinders made from the same sample of concrete.

Job	Class Concrete	No. Tests	Av. Diff,psi Lab A-Lab B	Std.Dev. Diff.
1	3000	8	-706*	506
	5000	9	-769*	365
	Both	17	-740*	424
2	4000	27	-754*	400
	6000	15	-513*	438
	Both	42	-668*	424

*Difference statistically significant at 1:100(.01).

Table 3. Difference in Compressive Strength of Cylinders from the Same Sample of Concrete Made and Tested by Two Different Laboratories

Each pair of labs (A and B) tested 6 to 10 samples at the rate of one or two samples per day.

Comparison No.	No. Tests	Diff. (A-B) psi	Std. Dev. psi
7	10	- 1	243
3c	10	- 6	248
4	8	29	174
3a	10	-40	165
3b	10	-70	125
10	6	152*	127
2	8	-163**	109
5	10	-226*	267
6	10	245**	100
1a	10	247**	97
8	10	249	527
1d	10	288**	207
1b	10	304**	69
1c	9	421**	130
9	10	588**	168

*Statistically significant at α = .05 (1 in 20)
**Statistically significant at α = .01 (1 in 100)

LABORATORY ACCREDITATION AS VIEWED BY A MANUFACTURING CONCERN

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ABSTRACT - Laboratory accreditation is judged to be both necessary and desirable. Accreditation provides an excellent means to assist in the selection of a commercial or independent laboratory. However, it should not be necessary for manufacturing concerns operating in-house laboratories to have their facilities accredited in order to test and certify their own products. The technical competency of most of these laboratories is already well recognized and needs no further verification.

Accreditation must be based on laboratory performance; staff qualifications and organization are secondary. Competent and knowledgeable assessors are the key to a good laboratory accreditation system.

The accelerating development of laboratory accreditation programs and systems during the past ten years has been viewed with some reservations by many companies which test for and certify product quality in their own in-house laboratories. The need for competent, reliable and independent laboratory analyses and inspections is accepted without question. However, for many, the need of an assessment and accreditation by an outside agency is judged to be of doubtful value.

Since the background and experience of the writer is almost entirely in petroleum refining, this paper deals largely with the assumption that the petroleum industry does not require accreditation of their in-house quality control laboratories in order to provide petroleum products of excellent and consistent quality. Accreditation is viewed as an unnecessary burden and expense.

Oil company laboratories have long enjoyed an enviable reputation for excellence in their operations. This has been achieved during the past forty years by the efforts of many dedicated people. There are several reasons for this achievement but the primary ones are as follows.

First, the industry through participation in ASTM and other standardization activities, has developed specifications for essentially all petroleum products which ensure customer satisfaction at minimum cost. These specifications have been established in cooperation with our customers, automobile and farm equipment manufacturers and government representatives. Of even more importance to laboratory operations is the fact that compliance with these specifications is assessed using a compendium of standardized tests and analyses, the precision of which has been established by cooperative testing involving many laboratories. Participation in these cooperative programs also provides a means to evaluate an individual laboratory's performance.

Second, most petroleum companies operate more than one refinery and have several quality control laboratories. These companies all have interlaboratory testing programs to evaluate performance and take corrective action as required. In addition, most petroleum quality control laboratories have access to the facilities of large, well equipped and professionally staffed central research organizations to provide assistance as needed. Consequently, the technical competency of these laboratories is assured, and there exists little need for further accreditation or acceptance.

While the technical competency of in-house laboratories is widely accepted, the question is frequently asked if these facilities have the independence and authority to report test data in an objective and unbiased fashion. This is, in most cases, completely irrelevant. Most companies make every effort to ensure the independence of their laboratories and delegate sufficient authority to their managers to eliminate pressures from the manufacturing operations. In-house laboratory managers recognize that the integrity of their operations is their major product and do everything possible to preserve it.

While the need for accreditation of in-house laboratories is rejected, there does exist a real need for a means of assessing commercial or private laboratories. Companies with excellent in-house laboratory facilities still have frequent need to utilize the services of commercial laboratories for specialized analytical work. The selection of laboratories for this purpose has been a difficult process, and occasionally a poor choice is made. There are several ways in which the competency of outside laboratories can be judged. Primarily, these include:

1. References and recommendations from other clients.
2. Membership in a recognized commercial laboratory organization such as the American Council of Independent Laboratories.
3. Submission of samples of known composition.
4. Personal acquaintance with the laboratory owners or managers.

It is usually possible using the above criteria to select a competent and reliable commercial laboratory for specialized work. However, considerable time and expense are involved in making a choice; mistakes are possible and can prove to be extremely costly.

The selection of commerical laboratories to perform specialized work will be simplified and accomplished with much greater confidence once laboratory accreditation systems are better recognized and in wide spread use.

Prospective clients will certainly be able to reduce time and effort in their selection. It is thus believed that laboratory accreditation is both desirable and necessary for commerical laboratories as a means of evaluating their competence. Conversely, there is no established need to require accreditation of most in-house laboratories testing their own products and who have already established their competence and integrity.

While strongly in favor of laboratory accreditation, there do exist some concerns about the way in which systems are developing. Criteria now being established place too much weight on the academic requirements for personnel, for independence and integrity, for the laboratory organization and for the handling of office routine. While these criteria are important, accreditation of a laboratory must be based on performance -- does the laboratory get accurate and precise results in a reasonable time at a minimum cost. The determination of performance must be accomplished either by analysis of known samples or by sample exchange programs with other laboratories. In addition, and probably most important, evaluation of the laboratory must be conducted by a competent and knowledgeable assessor. The assessor must not only understand the technology used but also must be able to evaluate the quality control and quality assurance programs in effect. It is these items which will measure the performance of a laboratory or inspection agency.

Another concern is the long time period required to accredit laboratories under existing systems. Also, most laboratories so far accredited have been those performing relatively few tests on a small number of products. Again, referring to petroleum testing laboratories, concern is expressed over the time and expense required to evaluate a laboratory performing 500 to 700 different analyses on over 500 different products. Hopefully, procedures will be established to minimize the time requirement. To reiterate, the assessor or assessors are the keys to a successful laboratory accreditation program.

In summary, laboratory accreditation is viewed as both necessary and desirable. However, many manufacturing concerns should not be required to have their in-house laboratories accredited in order to test and certify their own products. This does not mean that such laboratories should be excluded from obtaining accreditation if they so desire. Laboratory accreditation will continue to move forward; cooperation of all interested parties is necessary to achieve the best systems, and hopefully this will be achieved in the near future.

PROBLEMS CONFRONTING A U.S. FIRM EXPORTING A COMPLEX PRODUCT 1/

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ABSTRACT - In exporting farm tractors, a U.S. manufacturer must meet specific governmental regulations which vary from country to country. Regulations covering some 52 components have been identified. A review of the requirements in 30 countries indicates that some regulate most of these components while others regulate only a few. Government and industry need to work together so that test performed in the United States showing compliance to foreign regulations will be accepted by foreign government authorities.

In order to prepare a tractor model for export, we must first determine the specific governmental regulations affecting the design of the tractor which must be complied with in order to obtain approval to sell the tractor in various countries. This involves not only determining the regulations and compliance procedures for the tractor but also monitoring a continuing flow of new regulatory developments taking place in the legislative bodies of countries and certain national and super national organizations. To illustrate the magnitude of the problem, Figure 1 presents a list of 52 components on a tractor for which varying requirements exist in 30 different countries. Often the requirements on each component differ from country to country and actually preclude a common design. I have no exact figure for the number of characteristics of tractors that are regulated, but according to an article published in the British Standards Institute 10 years ago there are over 1500.

Some of the major items which require detailed precise tests during inspection are:

- Performance of roll-over protective structures;
- Characteristics of the engine smoke;
- Noise of the tractor (to operator and bystander);
- Operator station visibility;
- Tractor power with engine installed out of the tractor;
- Tractor braking;
- Strength characteristics of glass in tractor windows; and
- Tractor ride characteristics.

Prior to approval for sale in many countries, the tractor must be tested and/or inspected by authorities of the countries for compliance to the country's regulations. This process of inspection is called "Homologation."

Many countries require that the tractor be presented - or a number of identical tractors be presented from which the authorities will select one - to their various testing or inspection authorities for testing and certification of compliance prior to issuance of a permit to see that mode. This process is sometimes referred to as "type approval." In order to provide an uninterrupted supply of tractors to sell each time there is a substantial change or new model introduced, it is necessary either to stockpile current models while awaiting approval or to build very expensive prototypes sufficiently in advance of regular production to allow for the time required for homologation. If the manufacturer elects not to carry a heavy inventory, he may be required to build as many as 100 prototype tractors just to obtain the necessary certificates to gain selling approval for a new tractor line which conceivably may reflect say only a 5% power increase. The homologation process requires from a minimum of two weeks to 18 months depending on the country involved. Subjective interpretation of the requirements by inspecting officials can result in costly emergency changes in the product design which in turn results in production and sales delays.

I've only briefly touched on the problem facing a U.S. exporter of farm tractors to foreign countries. Now let's look at the reverse of that situation. An importer of tractors to the U.S. has to meet only one requirement involving federal certification; that is, the OSHA requirement 29CFR1928:51 for roll-over protective structures. To meet this requirement, the manufacturer must self-certify and add a message on the tractor that the roll-over protective structure on the tractor meets the OSHA requirements. Of course the manufacturer must be able to substantiate his self-certification with actual engineering test documents.

Further, the importer or manufacturer of the tractor can offer his product for sale in 49 of the 50 states with no other homologation requirements. The one exception is the state of Nebraska, where a tractor must undergo a power performance check to verify the power claims. Even in this case, the foreign manufacturer can obtain a temporary permit and offer the tractor for sale in the state of Nebraska until a time is set to test the vehicle at the Nebraska Tractor Test Laboratory. This test normally requires less than one week. No other state in the United States requires certification of any kind.

Do we see any hope for alleviating our export concern. I believe there will be some relief at least in European Economic Commission (EEC) or Common Market countries. The EEC has directives for twenty-eight requirements currently in place and is now taking action (to be concluded in several years) to establish requirement in a total of 44. To prove compliance with each the EEC requirements, the vehicle must be tested at an approved EEC test station in an EEC country. Today this inspection for compliance may require going to anywhere from to to ten different test stations because many of the test stations are authorized only to perform a select portion of the tests. This is both time consuming and costly. The relief mentioned is that having secured approval to a particular directive at one test station, all EEC countries are to honor this approval.

For us to remain competitive, our governmental agencies and industry need to work together. Because of attitudes in many importing countries, there are some functions involved in international trade that can be accomplished more efficiently by government. Then there are other functions that can be performed more efficiently by industry. To be competitive we must operate in the most efficient atmosphere. In order to accomplish this we need assistance in two areas.

1/ This paper has been summarized by the editor, based upon the oral presentation of the author at the workshop.

The first area in which we need assistance is in homologation. Here we need a means whereby the vehicle or product for export can be tested in the United States, and a document showing compliance to the regulations can be secured in the United States. To minimize time and expense, and to maintain pre-production product security, it would be more efficient to be able to homologate the product at a site having adequate laboratory facilities. To perform this homologation, considerable expensive laboratory equipment and qualified personnel are required. The laboratory facilities operated by the seven major agricultural manufacturers would probably be adequate. However, a system which verifies the performance capability of the laboratory equipment on which the tests were performed and the capability of personnel doing the test work is needed that would be acceptable to the importing country's authorities. It is here where I believe the NVLAP program or some form of laboratory accreditation offers possibilities.

The second area in which we need assistance is in documentation. There is a need for a system where the laboratory or inspection test results can be judged, and if they are found to meet the regulatory requirements, an appropriate notice of compliance can be issued. It is mandatory that this compliance statement be issued by an organization acceptable to the authorities of the importing countries or in some way acceptable to the European Economic Community.

I want to thank you for the opportunity to present and discuss a few of our problems. Hopefully this workshop will initiate some future means of solution.

Figure 1

Agricultural Tractor Product Legal Requirements

HOMOLOGATION REQUIREMENTS BY COUNTRY

	Algeria	Australia	Austria	Belgium	Brazil	Canada	Czeckoslovakia	Denmark	EEC	Finland	France	Germany	Ireland	Israel	Italy	Japan	Kenya	Luxembourg	Netherlands	New Zealand	Norway	Portugal	Russia	SAR	Spain	Sweden	Switzerland	U.K.	United States	Yugoslavia
Axle Loads			●	●			●	●	●	●	●	●			●	●					●	●				●	●	●		
Brakes			●	●			●	●	●		●	●	●		●	●			●		●		●			●	●	●		
Brakes, Trailer			●						●		●	●				●							●							
Cabs			●				●	●		●	●	●			●						●		●			●		●		
Chocks			●									●																		
Decals		●				●				●	●	●			●						●				●	●		●		
Defroster																							●			●				
Differential Lock			●							●		●														●	●			
Emissions								●																	●					
Engine w/accessories		●	●					●			●	●			●											●		●		
Engine Shut-off Cable										●											●					●		●		
Electrical Equipment			●								●	●														●				
Field of Vision									●		●	●																		
Footrest			●					●		●																●		●		
Fuel Tank				●					●		●	●														●				
Glass								●		●	●	●				●							●			●		●		
Handholds								●				●														●		●		
Heater										●		●											●			●				
Hitch, Front			●									●			●												●			
Hitch, Wagon				●											●												●			
Horn			●						●	●	●	●									●		●		●		●	●		
Injection Pump Seal																					●					●				
License Plate	●	●	●	●				●	●	●	●	●	●	●	●	●	●	●	●		●			●	●	●	●	●		
Lights	●	●	●	●		●	●	●	●	●	●	●		●	●	●	●	●	●		●		●	●	●	●	●	●		
Operator's Controls										●		●									●		●			●		●		
Mirror		●		●					●	●	●	●	●		●			●	●		●		●			●	●	●		
Muffler			●								●	●			●												●			
Noise		●	●	●	●		●	●	●	●	●	●			●	●			●		●	●			●	●	●	●		●
Parking Lock			●							●	●	●														●	●	●		
Platform												●														●				
Reflectors	●	●	●	●				●	●		●	●		●	●	●		●	●				●	●	●	●	●	●		
Rim												●									●									
ROPS		●	●	●		●	●	●	●	●	●	●	●		●			●	●	●	●					●	●	●	●	●
Safety Devices for Hyd. Equip.			●					●			●	●														●		●		
Seats, Drivers			●	●						●	●	●											●			●				
Seats, Passenger							●		●		●	●											●			●				
Serial Number Plates		●	●	●			●	●	●	●	●	●			●	●		●	●		●		●		●	●	●			●
Shields and Guards		●	●					●		●		●									●		●			●	●	●	●	
Smoke		●		●					●		●	●		●												●	●	●	●	
Spark Arrestor		●																					●			●			●	
Speedometer									●			●			●															
Stability			●								●	●														●	●	●		
Steering			●	●			●	●	●	●	●	●	●		●	●		●	●		●			●	●	●	●			
Steps										●		●											●			●		●		
Tires												●																		
Transmission Ratios			●						●			●															●			
Visibility				●					●		●	●														●				
Vibration										●		●																		
Weight for Ballast				●					●																					
Wheel												●																		
Width (vehicle)				●					●		●	●			●										●			●		
Wipers (windshield)				●					●		●	●											●			●		●		

Revised: 15 Aug 78

LABORATORY ACCREDITATION OF INTEREST TO THE NATIONAL CONFERENCE OF STATES ON BUILDING CODES AND STANDARDS

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ABSTRACT - The National Conference of States on Building Codes and Standards (NCSBCS) has supported laboratory accreditation since the early 1970's. Such systems should be voluntary, should encompass a peer group evaluation process, and should be acceptable throughout the United States. The voluntary laboratory accreditation systems must be monitored by a disinterested third party. NCSBCS wishes to become an equal partner in a voluntary laboratory accreditation system that continues to ensure the health and life safety of the residents of our states and for this purpose it is considering establishing an advisory group of state and local officials to keep everyone apprised of its interests.

The National Conference of States on Building Codes and Standards, Inc. (NCSBCS) is not a newcomer to the subject of laboratory accreditation. In fact, in the early 1970's, the Conference, through its committee structure, played a major role in the development of the Laboratory Evaluation and Accreditation Program (LEAP) in conjunction with the National Bureau of Standards (NBS).

In the essence of time, I am sure you will agree with me that the police powers granted in the Constitution of the United States rests between and amongst the states. Police powers in this case meaning the health and life safety of the citizens in new and existing buildings, including materials used in the various types of construction. Moreover, the concept extends to what I choose to call appliances such as solid fuel burning devices, space heaters, etc.

Standards development, laboratory accreditation, and product certification in the United States are for the most part, private sector activities. There is, however, wide spread use of private standards, laboratory accreditation and product certification by state and local governments for both regulations (e.g., building codes) and procurement. Hence, state and local governments have a definite interest in the system in that they have the ultimate responsibility for the health and safety of the citizens of their states and localities.

State and local governments must be assured that a system is in place that assures a minimum acceptable level for the performance, safety and the useful life of materials and products.

The NCSBCS has long been a supporter of performance based rather than prescriptive standards, but it should be noted that there are very few pure performance based standards. Failure, of course, is the only ultimate test of a performance based standard.

If the product under test performs as it purports to, then it is by definition, satisfactory.

There have been and will be instances wherein new products are developed and no nationally recognized standard exists. Moreover, new technology often cannot be adequately tested by existing approved testing methods. In these instances, states may be in a position of not being able to accept a product or system.

There are any number of state laws or local ordinances that deal with this subject and they vary from one jurisdiction to another, thereby placing a burden on not only the laboratories that test a product to assure its compliance to a nationally recognized standard, but on the manufacturer of a product as well.

Given the above, I believe it is relatively easy to see that "self certification" is going to meet with hostility.

Currently, we have in place a number of programs by various organizations and agencies of the federal government dealing with the accreditation of laboratories. Such programs as the Council of American Building Officials (CABO) Rules and Procedures for the Listing of Testing Laboratories, the Southern Building Code Congress International (SBCCI) Committee on Research and Compliance which includes an evaluation of laboratories, the Building Officials and Code Administrators International (BOCA) Testing Laboratory Evaluation, the International Conference of Building Officials (ICBO) Rules of Procedures for Issuance of Listing of Testing Agencies. In addition, we have the NCSBCS Laboratory Accreditation Program, the National Voluntary Laboratory Accreditation Program (NVLAP) and the American Association for Laboratory Accreditation (AALA) Program, and I am sure there are others.

The major thrust behind the NCSBCS Laboratory Accreditation Program is to use an inplace system if available. Such a system would include broad based representation on the organizations Accreditation Committee and following the American Society for Testing and Materials (ASTM) E548 "Standard Practice for General Criteria for Use in the Evaluation of Testing and Inspection Agencies" criteria.

The Conference has been meeting with representatives from AALA and NVLAP in order to develop participation by the states in their respective programs.

Just imagine for a moment, if you will, a building official at the state and/or local level receiving a report under each of the above programs that may differ as to its recommendation or acceptance of a testing laboratory.

I am sure that in each of the various laboratory accreditation programs of each of the organizations mentioned we will find a great deal of simularity. What is needed then is the following:

- A general agreement by all parties involved that a voluntary system of specialized or programmatic accreditation is highly desirable.
- Voluntary laboratory accreditation must be by a peer group evaluation process involving all interested, affected parties whom are technically qualified to develop the criteria under which a laboratory will be accredited and for what building products or appliances.
- A monitoring system of voluntary accredited laboratories in order to maintain the accredited status.
- A voluntary accredited system must be monitored by a disinterested third party to assure the voluntary accredited system is being maintained in the manner in which it was approved.
- Voluntary accreditated laboratories should be acceptable throughout the United States.
- NCSBCS is considering the establishment of an advisory group of state and local officials to keep the federal government and others aware of its needs and concerns related to building products and appliances being imported into the United States.

We are concerned that the language contained within the General Agreement on Tariffs and Trade (GATT) agreement (signatory nation to use their influence to gain acceptance of a product) wherein building products, materials and appliances are not subjected to the scrutiny of a properly accreditated laboratory.

In short, and in order to avoid proposed federal legislation or proposed rulemaking by the Federal Trade Commission (FTC) dealing with this subject, we must initiate a voluntary program that is acceptable to both the private and public sector.

I underscore the word "voluntary" since this is the nature of our system which is totally supported by NCSBCS policies. We do not wish to "rock the boat." Rather, we wish to become an equal partner in a voluntary system that continues to ensure the health and life safety of the residents of our states.

ADVANTAGES TO THE NUCLEAR REGULATORY COMMISSION OF THIRD-PARTY LABORATORY ACCREDITATION PROGRAMS

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ABSTRACT: The Nuclear Regulatory Commission (NRC) has expressed a strong interest in third-party laboratory accreditation. The advantages and disadvantages of a government operated (but not NRC operated) system such as the National Voluntary Laboratory Accreditation Program are described as relevant to NRC, the nuclear power industry and the affected workers.

The Nuclear Regulatory Commission (NRC) has expressed a strong interest in third-party laboratory accreditation which can be useful in the Commission's regulatory programs. This interest has arisen largely because of limitations on Commission manpower and resources, limitations that can be overcome in part through third-party accreditation. For example, in the health physics area the NRC requires of its licensees three types of radiometric measurements that involve laboratory analysis and are therefore of interest in discussions of laboratory accreditation. These measurements may be briefly described as follows:

(1) Licensees are required to measure the radiation dose received by workers from sources of radiation external to the body. These measurements are referred to as "personnel monitoring" or "personnel dosimetry." Normally, the workers wear a small dosimeter which is subsequently processed by a dosimetry laboratory to determine the dose received.

(2) Since some workers are exposed to airborne radiactive material, licensees are often required to perform laboratory measurements which estimate the amount of such material that has been deposited in the body. These measurements are called "bioassay." Biossay results are used to estimate the dose received from sources internal to the body.

(3) NRC licensees are allowed to release small quantities of radioactive material in effluents to unrestricted areas. Some licensees must periodically obtain samples from the nearby environment (air, water, soil, vegetation, etc.) which are subsequently analyzed for radioactive material content. Such measurements are usually referred to as "environmental monitoring."

Personnel dosimetry, bioassay, and environmental monitoring all require competent laboratory performance if an acceptable degree of accuracy and precision is to be achieved. Unfortunately, there is evidence that not all laboratories perform in an adequately competent manner.

It is the responsibility of the NRC to adopt criteria for the acceptability of these measurements and to make a reasonable effort to ensure that the criteria are met in NRC-licensed activities. Laboratory accreditation, based on performance testing and quality assurance inspection, appears to be the most suitable approach for a regulatory program. The procedure that can be used may be described as follows:

(1) The NRC requests the development of an appropriate consensus performance standard, including quality assurance criteria.

(2) A pilot study of the standard is conducted, using volunteer laboratories, to determine whether the standard is too lax or too stringent; any necessary adjustments are then made.

(3) The NRC requests a laboratory accreditation organization, such as NVLAP, to establish an accreditation program which includes periodic performance testing against the standard as well as periodic inspection of the quality assurance program.

(4) Once the accreditation program is operational, the NRC publishes a regulation stating that the required measurements are acceptable only if performed by an accredited laboratory.

The first stages of this procedure have already been initiated for personnel dosimetry and bioassay.

Such third-party accreditation, as performed by NVLAP, clearly has many advantages for the NRC:

(1) The Department of Commerce has the legislative authority to accredit laboratories.

(2) NVLAP will work with the NRC staff to develop a program compatible with NRC's needs.

(3) NVLAP is experienced in laboratory accreditation programs.

(4) The NVLAP accreditation process involves a comprehensive evaluation, including proficiency testing as well as inspection.

(5) NRC staff requirements are minimal, with no additional inspection duties.

(6) No long-term NRC financial commitments are necessary.

(7) NRC is not involved in disputes that may arise.

(8) NVLAP criteria include recordkeeping, calibration, employee training, facilities operation, and quality assurance. The NRC can essentially impose these requirements despite lack of authority over the laboratories.

(9) Confidence in the quality of the measurements is improved.

This approach allows the NRC to improve laboratory performance with minimum staffing and resources, allows initiation of a self-supporting program to test and certify technical competency, and allows establishment of uniform quality assurance criteria. Of course, third-party accreditation by NVLAP is not without disadvantages to the NRC. These include:

(1) NVLAP does not currently employ personnel with experience in these types of laboratory work. However, the Center for Radiation Research of NBS will provide all technical support needed in the developmental and operational stages of the program.

(2) Costs for NVLAP development of laboratory accreditation programs and possible costs for radiation sources must be paid by the NRC.

(3) This approach could be viewed as an expansion of Federal Government power over private industry.

(4) Laboratory performance against the final revised ANSI Standards is not always predictable. If the initial number of laboratories receiving accreditation should be inadequate, the NRC would be pressed for immediate relief.

With regard to other Government agencies, they can use these programs without sharing in the funding of the testing projects. In fact, they will probably be under pressure to enact similar directives or regulations as soon as possible.

These programs will also afford several advantages for industry:

(1) NVLAP encourages good laboratory practices and allows processors time to correct problems and deficiencies. It would be difficult for the NRC to permit such latitude.

(2) Better quality control should result in better performance.

(3) Employers need to know the accuracy of laboratory results since the results verify safety and regulatory compliance.

(4) Another major value of an accreditation program is credibility. Self-designed and -administered testing and quality control programs do not always carry the credibility of a nationally-recognzied accreditation program.

(5) Accredited laboratories have an advertising advantage.

(6) Commercial laboratories are tested routinely by their customers. An advantage would be a reduced number of customer tests, many of which are improperly designed and implemented.

There are, of course, disadvantages to industry:

(1) Mandatory accreditation to retain the business of NRC licensees will not be without initial and continuing costs.

(2) Failure to achieve accreditation or loss of accreditation would be a serious concern for a laboratory, possibly resulting in costly corrective action and loss of business.

(3) A licensee who fails to gain accreditation for an in-house laboratory would have to make new contractual arrangements with a commercial laboratory with current NVLAP accreditation.

(4) A testing program could discourage new developments. A laboratory with a procedure that will pass has less incentive to research and develop new techniques.

With regard to the affected workers, the following advantages may be listed:

(1) There is a trend toward recognizing the right of individuals to have information about themselves that is contained in records. Laboratory accreditation programs will lead to improvements in measurement accuracy and in recordkeeping. Workers have the right to know that their measurements are accurate and that the laboratory used by their employer is competent.

(2) When overexposures occur, documentation required by these programs will assist in rapid verification of measurement results, possibly assisting workers in litigation procedures.

(3) With the current concern over the biological effects of low level radiation, it is important that workers' doses be properly measured and documented.

Two disadvantages to workers have been identified:

(1) If a laboratory performing an employee's measurements fails to become accredited or loses accreditation, the employee's records will be questionable and may be of less support in any claim that arises.

(2) If the cost of laboratory services increases, employers who are not required to provide the services but do so voluntarily could terminate the services, resulting in a decrease in radiation protection.

There are a few advantages to laboratory accreditation for the general public. For example, public confidence would be improved because accredited laboratories would be required to participate in performance testing and also to maintain quality assurance programs. However, if a large number of laboratories fail to gain accreditation, the public may lose confidence in the abilities of other more competent laboratories. The most important disadvantage to the public is that they will indirectly pay the cost for these accreditation programs.

This analysis of the pro's and con's of NVLAP accreditation leads me to the conclusion that programs of this nature can contribute materially to radiological health protection in the United States at a cost that is small when compared with the benefit.

THE CONSUMER INTEREST IN LABORATORY ACCREDITATION

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ABSTRACT: The consumer interest in laboratory accreditation is by no means an easy and obvious interest to describe. It is based upon four fundamental consumer rights: the right to be informed, the right to choose, the right to safety, and the right to be heard. The characteristics which effective laboratory accreditation systems must have, based upon these four rights are described. The end use consumer is best served by systems which have the most integrity, have the most quality, are the most efficient and cost effective, display the greatest sense of public responsibility, and have the best accountability. The concept of NVLAP being an "accreditor of accreditors" might make a lot of sense but it would need to develop over a period of years in stages.

The consumer interest in laboratory accreditation is by no means an easy and obvious interest to describe. There has been very little written on the subject, and the few organized consumer groups that have been involved at all have spent most of their time dealing with standards development and certification, not accreditation. I say that as an observed fact, not as a criticism. As a matter of fact, I believe that the consumer groups have demonstrated a correct sense of priorities in diverting their limited resources towards standard development and certification issues, because I agree with them that the problems in those two areas are more immediate and pressing.

Nevertheless, there is a consumer interest* in accreditation, and I am pleased that I have been invited to share my thoughts with you on what that interest might be.

Whenever I am asked to discuss the consumer interest position, I find it useful to set forth, as a point of departure, the four consumer rights that have become widely accepted in our society. These four rights were first articulated by President John F. Kennedy, then reaffirmed by Presidents Johnson, Nixon, and Ford. Thus, they have been espoused for twenty years by both political parties.

As initially pronounced, they are as follows:

> "The right to be informed -- to be protected against fraudulent, deceitful, or grossly misleading information, advertising, labeling, or other practices, and to be given the facts he needs to make an informed choice.
>
> "The right to choose -- to be assured, wherever possible, access to a variety of products and services at competitive prices; and in those industries in which competition is not workable and Government regulation is substituted, an assurance of satisfactory quality and service at fair prices.
>
> "The right to safety -- to be protected against the marketing of goods which are hazardous to health or life.
>
> "The right to be heard -- to be assured that consumer interests will receive full and sympathetic consideration in the formulation of Government policy, and fair and expeditious treatment in its administrative tribunals."

Let me apply them to laboratory accreditation, and then see if a consumer interest position becomes more evident to all of you gathered here today.

The right to be informed: Under this heading we come face to face with the issue of the circumstances, if any, under which labs should advertise to the general public the fact that they have been accredited, and whether clients of labs should be allowed to so advertise.

A year or so ago, a group of consumer leaders met with John Locke and others in NVLAP to discuss this very issue. We did not all agree on the conclusion, but we did all agree that the question of advertising was a very tough issue to decide. On the one hand, all recognized that to the extent a lab accreditation system was well conceived and well administered, it could provide information to some end-use consumers that might be useful. On the other hand, there was considerable concern that if advertising were allowed, consumers would interpret the advertisement as a certification. While some argued that this fear could be allayed with an appropriate disclaimer, others felt that no disclaimer would work. My own view is that it is inherently misleading to allow clients of an accredited laboratory to advertise to the general public the fact that a consumer product has been tested by an accredited lab. The way to stop this is to insert such a prohibition in the contract, and for the accreditation body -- be it NVLAP, AALA, or anyone else, to make such a prohibition a criterion for accreditation.

The same problem does not exist for the lab. There is every good reason to allow accredited labs to indicate to potential clients the fact that their lab is accredited, provided it is never done in a misleading manner. The largest problem occurs when a lab is only accredited for some, not all tests. I would suggest that more thought be given to the uses of the terms "fully accredited" and "partially accredited," or "limited accreditation," to separate the two kinds of labs.

The right to choose: This right is more related to the issue of certification than it is to accreditation, but not entirely. As a general proposition, consumers are ill-served when monopolistic conditions exist. Where monopolies are necessary (for example, public transportation and public utilities), then generally consumers need a vigorous regulatory body to monitor the monopoly. (No matter what one's political views, and no matter how much one supports deregulation, it is hard to find anyone who would argue that PEPCO should be free to charge any rates it wished.)

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*For this paper, I use the term "consumer interest" to mean the interest of the end-use consumer/buyer, and not other consumers such as industrial users.

Given that general proposition, it follows that consumers are better off if the companies from whom they purchase consumer products have had an opportunity to have their products tested at competing accredited labs. Small business in particular is well served if they can rely on accreditation as an assurance of quality testing. Then and only then will the end-use consumer be best served.

Thus, the consumer interest is a second-level interest, but still an important one. There is too much evidence of the fact that monopoly leads to unjustified high prices -- and high prices are always passed on to consumers.

Having said that, I must add a caveat. Accreditation programs must not become so watered down as to be meaningless. First, they should only be put in place when there is a need for them. Second, they must not be administered in a way whereby everyone is always accredited. The two go together. If everyone is accredited, it is time to reconsider the need for accreditation in that particular test area.

By the same token, accreditation must be fair and unbiased, and it must be perceived as being fair and unbiased. No corners can be cut on this issue. I will have more to say on this at the end of this paper.

The right to safety: The accreditation issue raises no particular safety issues, except one with which you may not agree. I believe that accreditation bodies, be they government or non-government, are particularly well suited to play an influential role in upgrading the safety provisions of the underlying standards they rely upon. If an accreditation body were to use its prestige, influence and knowledge to feed back to standards developers any shortcomings they perceive in safety aspects of standards, then they would not only be performing a public service, but also would be enhancing their own prestige. I realize that some will say "that's not our business." But I would answer: if it's not your business, then don't kick and scream about the power of the safety regulatory agencies. Safety is too important to be left to chance and hope.

The right to be heard: Under this heading, let me address the issue that is on many people's minds today -- that is, the respective roles of the public and private sector. I have chosen to treat this under the heading "the right to be heard," because I believe that the interest of the end-use consumer on this issue must be taken into account.

As a consumer member of the AALA Board of Directors, I am well aware of the so called NVLAP/AALA issue. As my fellow board members know, I refuse to accept this issue as the main issue. While I have been involved in more than my share of so-called "turf" battles, I would like to see this one avoided. That is because it is unnecessary, and because it draws attention away from where the real efforts should be directed.

Let me be very blunt about it. Political philosophies aside, NVLAP could administer an accreditation program well or it could administer an accreditation program poorly. The same can be said about AALA or any other private sector system.

Thus the end-use consumer is best served by whatever programs:

- have the most integrity,
- have the most quality,
- are the most efficient and cost/effective,
- display the greatest sense of public responsibility, and
- have the best accountability.

Whichever programs score high in these five areas are in the consumer interest; whichever don't are not.

Not enough can be said about integrity and quality. Standards of excellence must be the basis for accreditation. By the same token, monoploy cannot be justified in the name of quality. I would be suspicious of any accreditation program that let every lab in; by the same token, I would be equally suspicious of any program that let in only the big, well-established labs.

By their very nature, government programs have a built-in accountability -- or at least they should have. Private programs like AALA's have to earn their acceptability by assuring accountability. That is one reason, I am sure, that AALA invited someone with my background to serve on their board. I was pleased that they asked and pleased to accept. It is one step toward accountability, but only one.

Whereas government programs such as NVLAP have a leg up on the accountability issue, private groups such as AALA can have an advantage in terms of efficiency and cost-effectiveness. All government programs must overcome the problems associated with bureaucracy -- in terms of costs, speed, and efficiency.

But no one should ever fool themselves to think that efficiency alone will be the basis on which the consumer interest will decide this issue. Certainly if, as the economists say, "everything else was equal." then surely the most efficient, least bureaucratic system is best. But first everything else must indeed be equal.

I come down this way. I am pleased as punch that AALA exists. I do not believe that NVLAP should be handed an exclusive charter in this field.

Neither do I believe that AALA should have any special status bestowed upon it. AALA, and all other private accreditation groups, need to earn their status.

Quality, integrity, and acceptability do not come overnight. They grow, and they are earned, and sometimes that is both a slow and a painful process.

I believe that the AALA concept of NVLAP being an "accreditor of accreditors" might make a lot of sense. I believe it worth exploring in great detail. But it is not a program for tomorrow, or even a year from tomorrow. It is a program and a relationship that would need to develop over a period of years, in stages. Perhaps what is needed is a long range plan, with a set of plateaus. As private programs such as AALA's become more established and demonstrate their quality, integrity and accountability capacity, then NVLAP can withdraw.

Three to five years from now, I would ask:

- Which programs discriminate against small labs?
- Which programs have the most vigorous investigatory systems?
- Which programs keep up-to-date with new technology?
- Which programs best control against misleading advertising?
- Which programs are most accountable?
- Which programs are most efficient?
- Which programs demonstrate a sense of the public interest?

Depending on the answers to those questions, I would then be willing to give a better response to the NVLAP/AALA issue.

If a number of the rest of the interests at this conference feel the same way, then maybe what should happen when this workshop is over is for a small, broadly representative group to sit down and prepare a five year plan with measureable achievement stops along the way. Then we could all get on with the effort to achieve these goals.

Session 4

WORK OF ASTM COMMITTEE E-36 ON CRITERIA FOR TESTING LABORATORY EVALUATION AND ACCREDITATION

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ABSTRACT: Since its formation in 1973, ASTM Committee E-36 on Criteria for the Evaluation of Testing and Inspection Agencies has been actively working to develop consensus criteria that could be used by others to evaluate and accredit laboratories. This paper highlights the activities of the Committee.

ASTM Committee E-36 on Criteria for the Evaluation of Testing and Inspection Agencies was established in 1973 in response to a recognized need for development of standards which could be used in the evaluation and accreditation of testing laboratories or other organizations. The committee is structured as a main committee, an executive subcommittee, and subcommittees with responsibility for criteria generation, nomenclature and definitions, and liaison. The major accomplishment of the committee has been the preparation of E548, the "Recommended Practice for Generic Criteria for Use in the Evaluation of Testing and Inspection Agencies." This provides guidelines for information disclosure in the categories of laboratory organization, human and physical resources, operational procedures, and quality assurance practices. It comprehensively identifies items about which evaluators and accreditors should seek information and upon which assessment of an organization's competence could be made. It does not specify minimum generic requirements which should be met by an organization in order to be assessed as competent.

While E548 has been widely referenced in many accreditation systems, the need for further work in establishing a basis for standardization in accreditation has been recognized. To this end Committee E-36 has embarked on the development of additional documents which together form a model accreditation system. The concept of a model can best be understood when accreditation is viewed in terms of its component elements, which include an accrediting authority, accreditation criteria, and an evaluation and monitoring process. The committee has structured these components into a model consisting of a framework of documents arranged in hierarchical order, as shown by the triangle of Figure 1. At the top of the triangle are generic guidelines for a laboratory accreditation system. An accreditation system can be thought of as an ordered arrangement of rules, procedures, and management which govern the Function of an accrediting authority. The system guideline identifies the elements and attributes which should be present in any accreditation system. A draft system document has been prepared by a Task Group of Subcommittee E36.10, the subcommittee within committee E-36 responsible for the development of generic criteria. The draft was discussed by the members of the subcommittee at its last meeting on October 20, 1981, and is currently being distributed to all subcommittee members as a letter ballot.

Much of the content of the draft is based on the work of the International Laboratory Accreditation Conference (ILAC). ILAC developed and adopted a similar document for use in comparing systems listed in its international directory of accreditation systems. To give some idea of the draft's content, following are a few of the attributes believed necessary to an accreditation system:

- It should specify accreditation of testing laboratories in terms of nationally or internationally recognized standards encompassing well-defined fields of testing, scientific disciplines or technologies or in relation to specific products or tests.
- Its technical criteria for accreditation should be formulated by persons with the necessary technical competence in the field of testing.
- Its criteria should be published and generally available.
- It should assess laboratories by using impartial experts in the area of testing for which accreditation is granted.
- Its assessments should include a written report from assessors.
- It should reassess its accredited laboratories periodically to demonstrate their continued competence.
- It should publish a list of accredited laboratories and the scope for which they are accredited, and should maintain a record of the tests for which each laboratory is accredited.

Every accreditation system involves an evaluation process. Guidelines for system managers are viewed as the second level from the top in the triangular model. These guidelines describe the characteristics of an evaluation process. A draft standard of these guidelines has also been prepared and is being distributed to Subcommittee members as a letter ballot. This document is viewed as a "how-to-do-it" guide containing information on how to conduct on-site reviews and audits, establish and conduct proficiency testing programs, and assess personnel, records, equipment, and calibration practices. It also provides criteria for the qualification and selection of assessors.

Generic criteria for use in evaluating and accrediting laboratories are shown in the model at the same level and adjacent to the Guidelines for the Evaluation Process. A draft document of this standard has also been prepared by the Task Group and is being distributed as a letter ballot. This draft is a significant departure from the existing E548 criteria standard and has generated much controversy within the Subcommittee. The new draft subsumes the information disclosure sections of the existing E548 and adds sections of generic requirements to be met by a laboratory or organization in order to be assessed as competent. The added requirements are similar to those contained in proposed revisions to the International Standards Organization (ISO) Guide 25, "General Requirements for the Technical Competence of Testing Laboratories." The philosophy for combining information disclosure and generic requirements into one document is to provide a basis for standardization of criteria and the possible harmonization of language among the dozens of accreditation systems now in existence. This standardization may provide the impetus for mutual recognition of accreditation systems and the attendant reduction of multiple evaluations to which many laboratories are subjected.

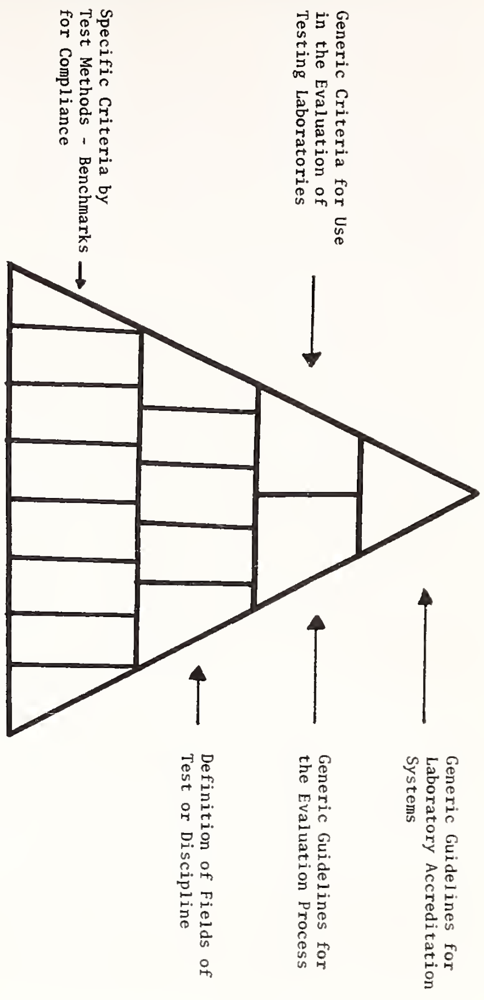
Generic Guidelines for Laboratory Accreditation Systems
Generic Criteria for Use in the Evaluation of Testing Laboratories
Generic Guidelines for the Evaluation Process
Definition of Fields of Test or Discipline
Specific Criteria by Test Methods - Benchmarks for Compliance

Figure 1. Laboratory Accreditation Model

It must be emphasized that the requirements which are included in this new draft standard are completely generic. For example, in the area of facilities and equipment, the draft states: "(The Laboratory shall) be furnished with major and ancillary items of equipment and facilities required for the correct performance of the tests and measurements for which accreditation is granted. Where relevant, adequate storage space for equipment and adequate facilities for recording observations must be provided." Specific criteria or, as they may alternatively be called, the benchmarks of compliance with the generic requirements, would be the province of an accreditor to establish for specific test methods depending on the particular needs of the accreditation system or the intended rigor and thoroughness of the evaluation. Alternatively, the specific criteria or the benchmarks for specific test methods could be established by technical groups or committees having responsibility for the test method. Within ASTM, for example, a technical committee having responsibility for a given test method may wish to add a laboratory evaluation apendix or addendum to the standard. Doing so would enhance the possibility for the uniform evaluation of a laboratory conducting the test regardless of the accrediting body, with the added potential for reciprocity among accreditors. Specific criteria are shown as the lowest level of the triangle in the model accreditation system. It is anticipated that Subcommittee E36.40 on Liaison would operate at this level to aid ASTM technical committees or other technical bodies to develop a consistent format for the specific criteria which would work with the generic requirements of the new draft standard.

The third level in the model represents the definitions of areas of testing or "disciplines" categorized in terms of test methods or procedures. Where logical groupings of test methods can be made, economy of scale in the evaluation of groups of similar methods may be possible. A new subcommittee of E-36 has been formed to establish guidelines in various fields of testing as related to accreditation, with the charge to develop the scope of the field of testing and related ASTM technical committees and test methods. This subcommittee held its first meeting on October 21, 1981, and is in the process of developing a work statement and scope. It must be emphasised that the subcommittee was established for the purpose of defining areas of testing or disciplines in terms of groupings of test methods, procedures, or techniques. The development of benchmarks of compliance or specific criteria for accreditation for specific test procedures would still reside with technical committees or groups having responsibilty for the test method or with the accrediting body, depending on its particular needs.

In summary, I would like to point out that Committee E-36 recognizes the need for more work in developing standards for laboratory evaluation and accreditation. Three draft standards have been introduced into Subcommittee E36.10 for letter ballot, and a new subcommittee has been formed to deal with the definition of fields of testing or disciplines. As in any organization, various interests are represented. So it is in Committee E-36. These new draft standards and activites are considered by some committee members as controversial and unnecessary; other members feel that the drafts represent exactly the type of material needed. Committee E-36, as in all of ASTM, operates on a consensus basis. This generally translates to compromise. At this time I can't predict the outcome or the form the new draft standards may eventually take, or whether final consensus standards will ever become a reality. I can, however, predict that a good deal of kicking and screaming will occur along the way.

CHARACTERISTICS OF LABORATORY ACCREDITATION SYSTEMS - THE PRODUCT CERTIFICATION PROGRAM POINT OF VIEW

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ABSTRACT: A product certification program depends on the accuracy and reliability of the testing laboratory as a basis for certification. The certifier needs accurate testing, within statistical limits, among the laboratories being used. The certifier should be able to accept test reports from accredited laboratories without hesitation. Accreditation will probably not play a substantial role in product liability actions. A viable acceptable accreditor must have technical expertise; competent personnel; ability to present or to transmit the latest methodology; organizational and administrative ability; and an assailable, unquestionable integrity beyond any reproach. The last requirement is the most difficult to provide, and when provided, leaves no need for being accredited by someone else.

Our society has generated a standard of living based on the mass production of our consumer products. No longer can we depend on workmen to perform their function as artisans, and the consumer is losing confidence that any product will serve adequately. One of the answers to these fears is the certification of products to comply with recognized standards. This trend can be seen by the proliferation of certification programs that exist in the marketplace.

A product certification program depends on the accuracy and reliability of the testing laboratory as a basis for certification. It is an integral part of the certification program that the product be in compliance with and remain in compliance with a nationally recognized standard. Unless the testing can be relied upon, the certification program has no basis and is therefore meaningless. It should be noted that many certification programs use multiple co-operative laboratories; ergo, there is a need to have assurance that all laboratories are giving the same results. Some certification programs use only in-house laboratories but have multiple installations, the same result being required in that all of the laboratories must get equivalent results. The conclusion is inescapable, there has to be some regulation of the testing agencies to see that they are generating equivalent information; i.e., accreditation. For the purposes of this paper, the relationship between a purchaser and his supplier is not considered an accreditation; an accreditation being defined as a systematic approach to universal acceptance by numerous parties.

I think it is wise to discuss, at this point, what we mean when we say "laboratory accreditation." Most of you here think in the terms of a testing laboratory (chemical, mechanical, biological, etc.) and I would guess that all the talks in this conference will discuss testing laboratories. It would be wise to keep an open mind as to the extent of the accreditation under consideration. There are several certification programs which are presently under accreditation systems by both the governmental and private sectors. There is, I believe, some indication that design evaluators or evaluative agencies may be subject to accreditation. I would therefore suggest that the term "laboratory accreditation" is not the generally conceived narrow term, but is a broad term which may encompass all agencies performing or using test data.

When asked to prepare this paper, there were four areas that were to be covered:

1) A certifier's concern for adequate testing
2) Relationship between a certifier and testing laboratory
3) The question of product liability
4) Minimum requirements for accreditation

It is my intent to make some very short remarks on the first three topics but to reserve the bulk of this paper for item number 4 which is of great concern to all of us here.

A certifier has absolutely no concern for adequate testing. He needs accurate testing. He needs testing results which are comparable, within statistical limits, from laboratory to laboratory. He needs to be able to rely on the results from any approved laboratory as being the basis for his certification. He needs laboratories which have a proven ability to give him these results, so that it makes no difference from whom the results come; they will be comparative. The certifier needs an accredited laboratory, hopefully accredited by some agency that will have the wherewithal to function properly.

What should be the relationship between the certifier and the testing laboratory? The less, the better. If the laboratory has been properly accredited, the certifier should accept such accreditation as prima facie evidence of acceptability. He should accept test reports from an accredited laboratory without hesitation unless it becomes apparent that there are discrepancies, in which case the accreditor should be informed and requested to make a determination. I would not foresee any reason for an additional relationship. But if the laboratories are not accredited, it becomes a question of either the certifier accrediting them or of not using them at all. If the certifier is to be the accreditor, a contractural arrangement becomes necessary and a whole relationship has to spring forward to establish the acceptability of the laboratory, how he disaccredits, the limitations of the accreditation, how the accreditation is maintained and at whose cost. This relationship becomes a little sticky when the certifier is, at the same time, a testing laboratory.

As to any questions concerning product liability, the relationship between manufacturer, certifier, testing agency and consumer are of such a myriad that it cannot be discussed or even the surface scratched in any reasonable period of time. Suffice it to say that I have not heard of any testing laboratory or certifier (non-manufacturing) being stung where only performance has been involved. On the other hand, I have heard of several instances where certifiers of safety related items for safety only, or who have held themselves out as safety certifiers, have been held liable. In my opinion, the contractual arrangements between the parties will establish the product liability responsibility, with the claims made by the certifying agency and the manufacturer but I do not foresee that accreditation will play any substantial role in product liability actions. Of course, in a courtroom, an accredited certification agency will have more credibility than a non-accredited one.

Now to the main area of this paper which is a discussion of the minimum requirements for an accreditation system. In its simplest form, an accreditation system is composed of an accreditor, an accreditee and criteria/methodology to effect accreditation. The accreditee is an applicant, well defined and understood, posing no problems in definition. The accreditee, in order to be accepted by the system must comply with the established criteria through the methodology established. Both the criteria and methodology are not in serious contention since we can look to standard references for them. ASTM has in place several such documents at the present time, most of which are based on a generic document (ASTM E-548) promulgated by ASTM Committee E-36. Specific documents are becoming more available as evidenced by ASTM E-541 (originally promulgated by ASTM's E-32 committee) and ASTM E-669 (by committee E-6) but additional documents of a similar nature are available from other committees. Additional methodology is available through NVLAP and the experience of various other countries in establishing accreditation programs. The real question is, "Who is to be the accreditor and what are his minimum requirements?" It is with this basic question that the balance of this paper will deal.

As a certification program operator, I want the accreditor to have:

1) Technical expertise.
2) Competent personnel.
3) Ability to evaluate present or to transmit the latest methodology.
4) Organizational/administrative ability.
5) Unassailable, unquestionable integrity beyond any reproach.

Give us an organization that meets these five criteria and, in my opinion, you have a viable, acceptable accreditor. Note that I have not injected cost into these parameters because I think that, although the costs have to be reasonable, in the overall picture, the cost will be a minor part of any laboratory or agency budget as long as the five basic requirements are being met and the accreditor is not trying to be a profit making organization (such an approach would violate requirement #5).

I know of no one who would question the availability of either technical expertise (#1) or of competent personnel (#2) in this country. If an accreditor does not have it on staff he surely could acquire it without difficulty, on either a full time or part time basis. Specific expertise is probably not necessary since competent personnel will quickly achieve sufficient expertise in almost any well written test procedure. Additionally, the organizational writers of the test procedures are available for consultation. To me, these items represent small problems for the accreditor since these items are self evaluating, as each accreditee would be more than glad to tell the accreditor when there is incompetence or lack of expertise. The bigger problem will be in the organization aspects of the accreditor to accept, recognize and react to such criticism. You will note that I give little consideration to personnel and their competence since this is only an administrative function, and any organization incapable of hiring proper personnel will most certainly not comply with requirement #4 -- Organizational/administrative ability.

Included in my list of requirements as #3 is the ability of the accreditor to present and transmit the latest methodology. I don't look upon accreditors or their personnel as "policemen" but as evaluators and communicators. They should be able to keep their clients informed as to the latest developments in technology. Almost as important, they should be able to report back to standards writing agencies what is actually occurring in real life which input should be invaluable in maintaining up-to-date methodology.

It is most important that any accreditor have both the organizational and administrative ability (#4) to not only handle the day-to-day operations of accrediting but, to create an organization which is self-evaluating, open minded and provides the prerequisite standards of appeal that must be inherent in the accreditation system. One cannot overstress the impact of accreditation. A removal of accreditation or a denial of accreditation can be devastating to the affected laboratory. It is, therefore, imperative that the organization of the accreditor be capable of ascertaining the propriety of any such move. Additionally, the accrediting agency must be administratively flexible enough to accept criticism and to react to it in a positive manner, particularly wherein there are complaints concerning the propriety and expertise of the field evaluators. The basic philosophy has to be one of getting the job done right, not in protecting the accreditor's organization. There are several factors which can be established that are pertinent to any accrediting organization. It cannot be controlled by those being accredited or by a small group of interested parties. It must be staffed with professional people whose proven function is to provide excellence in accreditation and not to preserve the status quo. There must be a mechanism of appeal to take care of honest differences of opinion and interpretation. The relationship between accreditor and accreditee has to be one of mutual respect and trust engendered by the ability of both organizations to work together to create a viable system of international repute. I guess this area ties in a great deal with the last item, but to me, it is the essential requirement for any accreditor.

We now get to what I consider the most important, absolutely essential requirement for any accreditor -- the accreditor must be an organization of unassailable integrity beyond reproach. In order to understand the essentiality this requirement we have to ascertain what effects that the accreditor can have on the laboratory. Regardless of any disclaimer, the denial of accreditation is a very serious blow to any organization. Even more of an effect would be the removal of accreditation from a laboratory. A laboratory in particular is dependent on its reputation as the basis for its continued existence. How can that reputation be maintained if accreditation is denied or removed? Even though we may be talking about only specific tests or areas of expertise, the spill-over on the laboratory reputation will affect its entire operations. And we have to be realistic, in accreditation programs, therefore, it must be anticipated that there will be denials and removals of accreditation. It is not enough to say that an appeal can be had because once a denial of approval is made, the laboratory's reputation is already tarnished. It is, therefore, of the utmost importance that the accreditor shall not be questioned as to his motives or as to his integrity or as to impartiality; i.e., THE ACCREDITOR MUST BE AN ORGANIZATION BEYOND REPROACH.

There must be no indication or affiliation that the accreditor has a financial axe to grind. There must be no indications that the accreditor is interested in "cutting-up-the-pie" or making available increased business by putting all laboratories on an equal basis. If these are the primary purposes of accreditation, we don't need it; nor do we need that type of accreditor. What we do need is accreditation based on upgrading the entire testing field, one that is operated for the benefit of the client, industry as a whole and for international recognition but not for the benefit of laboratories or for any association. This can only be achieved when our accreditation system and the accreditors have an unassailable, unquestionable reputation beyond reproach.

Are there organizations who can fill this requirement? In my opinion, there are very few but I believe that they do exist. For example, the National Bureau of Standards or ASTM would fulfill this requirement without question. ANSI could be considered as another candidate to be an accreditor. At least, these three organizations come to mind as suitable candidates meeting the "beyond reproach" requirements.

I am sure that there are other organizations which you could suggest. Suffice it to say that there are existing organizations available. You will note that the organizations listed have no involvement with the laboratory industry and it is my belief that no organization based on laboratory membership can ever become an accreditor because its base is inherently suspect and will never comply with the "integrity beyond reproach" requirement.

That leaves us with the situation as to whether an organization can achieve the "beyond reproach" requirement by another means; i.e., by itself being accredited by an organization beyond reproach. (I understand that such a proposal was the initiating force in this symposium.) I do not understand the philosophy of accrediting accreditors. If we accept the basic requirement that an accreditor has to be an organization "beyond reproach," then there is no need to accredit him since by definition his work is of unquestioned integrity. If he needs to be accredited, he has admitted his work is not of unquestionable integrity and that his reputation is not beyond reproach. To me the answer is obvious, once an organization has to request accreditation as an accreditor in order to achieve acceptance, it has admitted that it cannot comply with the requirement of unassailable, unquestioned integrity beyond any reproach.

Nor can an organization drape itself with a mantle of integrity and reputation beyond reproach by seeking acceptance through an additional layer of accreditation. Accreditation can only evaluate the ability to perform a function in an objective sense. It cannot determine the subjective evaluations as to whether the accreditee will utilize his abilities properly, or whether self-interest will raise its ugly head, or whether there is an active intent to utilize the accreditation in an improper manner. Integrity and reputation cannot be granted but must be earned by repeated performance as recognized by all whether involved or not. One does not don a coat of integrity beyond reproach, one earns it by performance and ability over a long distinguished period of operations as evaluated by his peers and by the public. Meeting the integrity beyond reproach standard cannot be coattailed upon accreditation.

Although this sympsoium has been initiated by the proposal submitted by the ACIL/AALA petition, I have preferred to make my commentary on a general basis. I don't think that it is necessary to inject any individual personality into this discussion nor should it be necessary. From the tone of my remarks, you can ascertain that as much as I would like to see the government not take the primary role in laboratory accreditation, it will be necessary for them to do so, unless organizations like ASTM or ANSI or some similar organization steps forth to fill the void.

GENERAL GUIDELINES FOR A LABORATORY ACCREDITATION SYSTEM

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ABSTRACT - This paper outlines the general criteria for establishing a laboratory accreditation system. It is consistent with the work done by Task Force C of the International Laboratory Accreditation Conference (ILAC). The guidelines, as contained in this paper, have been endorsed by the Board of Directors of the American Association for Laboratory Accreditation (AALA).

The purpose of this paper is to summarize and emphasize the work done by Task Force C of ILAC to develop guidelines for the operation of laboratory accreditation systems. It is entirely consistent with the presentation just made by Dr. Berman. Members of the Board of Directors of AALA have served on Task Force C, and AALA is comfortable with the guidelines recommended by Task Force C during the recent ILAC meeting in Mexico City. The guidelines are recommended for use by NVLAP in its proposed role as an accreditor of accreditation systems.

The guidelines identify the necessary elements and attributes of laboratory accreditation systems. They are designed to be used in conjunction with general, technical criteria for accrediting testing laboratories and guidelines for selecting assessors, conducting proficiency tests, and calibrating laboratory equipment. They will be used as a guide in the accreditation system established by AALA.

The laboratory accreditation system must not only apply rigorous criteria to evaluate its accredited laboratories, but must also possess the following key operational requirements.

The system must, of course, be actively engaged in the accreditation of testing laboratories. In this regard a testing laboratory is understood to be one which measures, examines, tests, calibrates, inspects, or otherwise determines the characteristics or performance of materials or products.

The system should accredit in terms of nationally or internationally recognized or other well-defined standards and test methods within well-defined fields, scientific disciplines or technologies. Accreditation is a formal recognition that a testing laboratory is competent to carry out a specific test or specific types of tests.

Technical criteria for accreditation should be formulated by persons possessing the necessary technical expertise in the relevant field of testing, and the criteria used for accreditation should be published and generally available.

It is also assumed that the criteria will be consistent with the International Organization for Standardization (ISO) Guide 25, presuming the satisfactory outcome of the current ISO/ILAC revision of Guide 25.

Laboratories should be assessed using impartial experts, singly or in teams, who have both substantial experience and expertise in the area of testing in which accreditation is sought and also in laboratory assessment techniques. Assessors are in many ways the key to an effective laboratory accreditation system, and the criteria by which assessors are chosen must be clearly defined and rigidly followed. It is also necessary to exercise extreme care to avoid even the appearance of conflicts of interests as far as laboratory assessors are concerned. The accreditation system must include a written assessment report from the assessors and also should feature a broadly based, impartial body such as the AALA Accreditation Council, which reviews the report and acts as the technical accrediting authority within the accreditation system.

Continuous reaccreditation is necessary in the system to demonstrate the continuing competence of accredited laboratories. Reaccreditation can include a variety of activities and need not require physical inspection every year. Other requirements such as notification of key personnel and equipment changes, proficiency testing, including round-robin, and inspections by other authorities can or should be accepted by the laboratory accreditation system during the interim period between physical reaccreditation assessments. Physical reassessments, however, must be performed with sufficient frequency to ensure competence in both the laboratory and credibility in the accreditation system.

A list of laboratories should be published and should include the general features of the accreditation system itself, the general capabilities of each of the accredited laboratories and the scope for which they are accredited, and finally a record of the tests for which each laboratory is accredited. A companion publication to the published list of accredited laboratories should be a precise policy dealing with advertising by accredited laboratories. The advertising policy should permit use of the accrediting system logo or trademark and should specify the accompanying citation to be used by laboratories on stationery, calling cards, laboratory reports or other acceptable forms of laboratory advertising.

The system should have fully documented procedures defining the accreditation system and including a contractual arrangement between the accrediting authority and the accrediting laboratory. Documentation should include evaluation procedures for initial and follow-up assessments for dealing with noncompliance of laboratories both in a technical sense and in any advertising being done by the accredited laboratory.

In summary, the laboratory accreditation system must be logical and consistent and feature complete and technically accurate documentation; impartial and technically competent assessors; and clear, understandable, and enforceable policies.

THE IEC'S WAY OF EVALUATING CERTIFIERS IN PARTICIPATING COUNTRIES

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ABSTRACT: The International Electrotechnical Commission (IEC) has developed the IECQ certification system on electronic components, including products such as resistors, capacitors, printed circuit boards, integrated circuits and connectors. A National Supervisory Inspectoriate (NSI) in each country was examined by the National Supervisory Inspectiorates of three other countries. In the United States, the NSI will evaluate laboratory and test facilities, in conjunction with an evaluation of the entire quality assurance system used by the manufacturer. Procedures used to evaluate the testing laboratories are described.

As a prelude to a discussion of the IECQ method of evaluating certification bodies, I would like to very briefly describe the IECQ system. Without going into all of the history, the IECQ system has been under development for approximately eleven years. It was started because a regional system in Europe was perceived as a potential barrier to the export of components from the U.S. to Europe. It is an international certification system on electronic components, including such products as resistors, capacitors, printed circuit boards, integrated circuits, connectors, and similar items.

Time does not permit a complete description of the organization and operation of the system, but it is necessary to understand some of the basic procedures before explaining how laboratories are evaluated.

In each of the countries participating in the system, an organization known as the National Supervisory Inspectorate has been appointed. Manufacturers in each country may submit their electronic components to the NSI for evaluation in accordance with a standard covering the component and approved within the system. The NSI will conduct a survey of the manufacturer's facilities, review his quality assurance program, and supervise qualification tests. If the results are acceptable a certificate of conformity will be issued. It is anticipated that, under this system, purchasers of the components in other countries will then accept the certificate of conformity as evidence that the product complies with the specified standard.

The national organization operating the system in the United States is the Electronic Component Certification Board, made up of six members from the component industry, four members from companies that are users of components, and five members at large. The ECCB has appointed Underwriters Laboratories to serve as the NSI for the United States.

Approval of all of the National Supervisory Inspectorates participating in the system was necessary before the program could be inaugurated. Each National Supervisory Inspectorate was examined by the national supervisory inspectorates of three other countries. The examination teams which visited each NSI did not accredit laboratories, but instead determined that the NSI had the capability and experience needed to supervise both the initial testing or qualification of the components, and the subsequent continuing inspection program at the factory of each participating manufacturer.

As a basis for the evaluation by the examination teams, each NSI prepared a national statement of surveillance arrangements. This explained in a considerable amount of detail how the system is intended to be operated in that country. The document prepared in the United States indicated how the NSI would evaluate a manufacturer's capability to produce the component in a uniform manner. This would include an assessment of the factory organization, especially the relationship between manufacturing and quality assurance. There would also be a complete evaluation of the manufacturer's quality assurance program.

The document lists all of the steps to be followed in qualifying components. The tests are conducted using the facilities of the manufacturer's laboratory or an independent test laboratory. If the results of these tests are acceptable, the manufacturer can begin use of the certificate of conformity. The national statement describes the basis for the evaluation of the manufacturer's continuing program of testing and inspection of the components. The document also lists all of the equipment available to the NSI for the conduct of audit tests, as well as detailed information about the qualification of staff members.

When the examination teams visited UL, they reviewed the national statement of surveillance arrangements. They also verified the qualifications of the individuals assigned to the NSI function. All of the UL staff members who will be involved in the qualification testing and surveillance inspections are graduate engineers with experience in the field of component testing.

The examination team also witnessed the way in which NSI staff members supervised a complete test program for the qualification of a component. For the purposes of this demonstration, a tantalum capacitor was tested in accordance with provisional IEC specifications. Additionally, we demonstrated the capability of testing an integrated circuit component. We were also required to demonstrate we had the capability to test all of the other components covered by the system. Additionally, the team verified the acceptability of the laboratory equipment at UL, which would be used for audit tests of components. This included a demonstration of the equipment, using actual samples of the components for test.

The examination team spent one week in the United States, visiting UL Laboratory facilities and observing qualification testing of components at a factory. The final report which was issued indicated that the team agreed that UL had the personnel, facilities, and operating procedures capable of operating the certification program in the United States.

When the program is in operation in the United States, UL will evaluate laboratory and test facilities, in conjunction with an evaluation of the entire quality assurance system used by the manufacturer. We have developed specific procedures to accomplish this. In addition to reviewing the quality assurance manual provided by the manufacturer, we plan to ask for information about the laboratory. We plan to use a survey form which will enable the manufacturer to provide information, to assist in determining whether or not the laboratory has the capability of carrying out the tests required under the system.

Equipment needed by each laboratory will be determined on the basis of the standards used in testing the component. We will compare the list of equipment included on the survey form with the specifications for the equipment needed to conduct the tests required by the component specifications, to determine the acceptability of the equipment. We will also judge whether the accuracy of the equipment is in accordance with the limits specified in the standard.

During our evaluation visit to the laboratory, the information on the survey form will be verified. At the same time compliance with additional criteria will be judged, including such factors as environmental controls, and the availability of detailed test procedures at each testing station. Each item of laboratory equipment will be checked to determine when it was last calibrated. The evidence of calibration must be traceable to the National Bureau of Standards.

The survey form also provides the NSI with information about the responsibilities and qualifications of the individual designated to be the manufacturer's chief inspector. This is the individual which the manufacturer has designated to be responsible for the accuracy of tests and measurements conducted by the laboratory under the system. During the visit to the laboratory, the information about his qualifications will be verified, along with the qualifications, such as education and experience, of other personnel associated with the tests.

In addition to the evaluation of equipment and personnel, the method used by the laboratory for controlling the quality of inspections and tests is evaluated as part of the overall quality program submitted by the manufacturer. This will include an assessment of the quality organization, control of the inspection and test operations, and the calibration system. It should be noted that the laboratory is considered an integral part of the quality system.

Additionally, we will review the way in which sampling is controlled, as well as the control of records and data and all other documentation. This will include information about the procedures for handling failures, nonconformance related to test equipment or procedures, and any corrective action necessary for the operation of the program.

There are several important elements in this program which should be emphasized. First of all, the laboratories' capabilities are judged in connection with a specific product category, and in accordance with the requirements for tests covered by the standard for that product category. As a manufacturer decides to have additional types of products covered under the program, a new survey will be required to determine whether a laboratory has the capability to test components in the new product categories. Laboratories will not be approved on the basis of general criteria, covering many product categories.

Another important factor is the relationship between the laboratory test program and the quality assurance program at the factory. The assessment of the laboratory including both equipment and personnel is a part of the overall assessment of the manufacturer's quality assurance system. The assessment of the laboratory cannot be isolated from an evaluation of the total program used by the manufacturer to assure that components conform to the requirements.

A third, and very important element, is the ongoing surveillance program conducted by the NSI. At least once each year, staff members from the NSI will visit the factory and the laboratory to verify that the manufacturer's program continues to comply with the requirements of the system. This will include a review of all test records, and a reassessment of the way in which the quality assurance program functions. There will also be a complete review of the laboratories' personnel and equipment.

Limitations of time have prevented a more detailed description of the IECQ system, but it is hoped that the foregoing material will give a better understanding of how laboratories are evaluated as part of the total quality assurance system in the IECQ program.

ILAC : A MEANS FOR REMOVING TECHNICAL BARRIERS TO TRADE BY RECOGNIZING LABORATORY ACCREDITATION SYSTEMS IN DIFFERENT COUNTRIES

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ABSTRACT - ILAC seeks first to promote the development of national programs for accrediting test laboratories, employing harmonized accreditation criteria, and then to promote the development of agreements by which importers will accept the results of tests made by accredited laboratories in exporting nations. An ultimate objective for ILAC may be to promote development of a treaty or worldwide agreement, possibly along the lines of the GATT code, by which signatory nations will agree to (a) operate national programs for accreditation of their test laboratories, (b) perform tests in accordance with mutually agreed upon standards, and (c) evaluate laboratories in accordance with mutually agreen upon criteria. Achievement of the foregoing objectives will serve to reduce or remove technical barriers to trade in the form of tests made by importers which are unnecessarily duplicative of tests made by exporters.

ILAC is an acronym for "International Laboratory Accreditation Conferences" (a foreshortened version of the original, more descriptive designation, "International Conference on Recognition of National Programs for Accreditation of Testing Laboratories"). Starting in October 1977, five annual ILAC conferences have been held, successively, in Copenhagen, Washington (1978), Sydney (1979), Paris (1980), and Mexico City (1981). The next two ILAC conferences have been scheduled for Tokyo (1982) and Prague (1983), with London and Tel-Aviv expected to host the conferences in 1984 and 1985.

A total of 42 countries and 12 international organizations have sent delegations to one or more of the conferences. In the intervening months between the plenary sessions various task forces and working groups have carried on several relevant lines of investigation and developed proposals in accordance with mandates given them at the annual meetings. One of the working groups was established by the Paris conference to develop and report to the Mexico City conference on "Information on Bilateral or Other Agreements for the Recognition of Laboratory Accreditation Systems." Following is a concise summary of the report of that group as it was presented last month in Mexico. The summary will describe the current status of international agreements recognizing laboratory accreditation systems in two or more countries, as well as efforts under way to develop international guidelines for judging laboratory accreditation systems that conceivably would form the basis for such international agreements.

Two bilateral agreements, each involving a different pair of countries, are known to be in actual operation. One agreement, in effect since July 3, 1979, involves Czechoslovakia and the German Democratic Republic. The other agreement, entered into on May 29, 1981, involves the Testing Laboratory Registration Council of New Zealand (TELARC) and the National Testing Authority of Australia (NATA).

The Czechoslovakian-GDR agreement concerns the mutual recognition of the test results of the State Quality Control for certain selected products which are exchanged between the two countries.

The TELARC-NATA agreement stipulates that each of those organizations recognizes the accreditation of testing laboratories by the other as equivalent to its own act of accreditation, and accepts for its own purposes test reports issued by laboratories accredited by the other organization on the same basis that it accepts test reports from its own accredited laboratories.

Czechoslovakia has further advised that negotiations for agreements similar to the one it has with the German Democratic Republic have been underway since 1980 with Bulgaria and the U.S.S.R., and Hungary has indicated interest in forming a similar agreement with Czechoslovakia. The Czechs have also advised that they are in the midst of negotiations for another agreement with an unnamed Western European country.

The Danish National Testing Board has not entered into any formal arrangements with accreditation systems in other countries for mutual recognition of test reports from their accredited laboratories. Nevertheless, test reports from laboratories accredited by the Danish agency are known to be accepted on a unilateral basis by different foreign bodies. TELARC, for example, recommends to parties in New Zealand that the technical validity of the Danish accredited laboratories' test results is comparable with that of TELARC's accredited laboratories.

The European Free Trade Association (EFTA) has a Pressure Vessel Scheme which is based on the principle of recognizing testing done in the country of exportation, although the approval of the goods still rests with the importers. The approving function thus is not dependent upon the outcome of the testing function, but it is interesting to note that certain specific requirements need to be satisfied by the laboratories, and the authorities in the exporting countries are involved in the assessing and recommending of laboratories for acceptance by the authorities in the importing countries. In 1970, incidentally, EFTA established a Convention for the Mutual Recognition of Inspections Regarding the Manufacture of Pharmaceutical Products. To date, Austria, Denmark, Finland, Hungary, Iceland, Ireland, Liechtenstein, Norway, Portugal, Sweden, Switzerland and the United Kingdom are signatories to the convention, and the Federal Republic of Germany and Romania are expected to be added shortly.

In the field of calibration significant progress has been made in the direction of achieving mutual recognition of certificates issued by national calibration services in various countries. In 1973 an organization known as the Western European Metrology Club was formed by the directors of the National Standards Laboratories in Western Europe. This club formed the Working Group Calibration Services (WGCS). In April 1980 the WGCS announced an agreement regarding "International Acceptance of Calibration and Measurement Certificates," and in June 1981 published a supplement containing certain minimum requirements for mutual recognition of their certificates. Also within the past year the heads of the national calibration organizations in the U.K., West Germany, the Netherlands and Italy agreed on the form of a declaration according to which the equivalance of the certificates of the respective calibration services could be recognized.

Conclusions and Recommendations of the ILAC Working Group

The ILAC Working Group on Bilateral Agreements concluded from its initial study that reciprocal recognition of accreditation systems and mutual acceptance of test data across international boundaries are possible when national bodies or authorities are involved.

The agreements thus far reviewed essentially fell into two categories dealing with:

1. Mutual acceptance of test data without the existence of laboratory accreditation systems; and
2. Reciprocal recognition of laboratory accreditation systems with the possible consequence of mutual acceptance of test data.

The first category, illustrated by the agreement between Czechoslovakia and the German Democratic Republic, is obligatory for governmental authorities. The second type, illustrated by the TELARC-NATA agreement, is not obligatory; it deals exclusively with technical competence and impartiality, and has no direct bearing upon governmental policy concerning recognition of test results, quality marks, certificates, etc. (The working group, incidentally, noted its understanding that its task primarily was to focus on category 2 type agreements and on ILAC's primary objective which is to facilitate international trade in proucts or materials by removing technical barriers.)

The working group requested ILAC/81 to authorize it to continue its study, and to develop a set of guidelines which could serve as the basis for any bilateral or other mutual recognition agreement. The basic areas of consideration recommended for such guidelines essentially would be along the following lines:

1. Prerequisites for an agreement:
   a. The accreditation systems should be described in a document which is publicly accessible.
   b. The scope of accreditation should be clearly stated.
   c. The national authority should be competent to enter into mutual agreements.
   d. The national authority should represent the respective scope of testing involved in the agreements.
   e. The accreditation system must fulfill the criteria for accreditation endorsed by ILAC.
2. Items to be covered by the agreement:
   a. A communication channel should be established and the international contact point be identified.
   b. A channel should be established to transmit information on accredited laboratories and their fields of expertise.
   c. Provisions should be made whereby one party may request the other party to provide additional information concerning the test results or services furnished by a particular laboratory.
   d. Provisions should be made whereby experts of the competent authorities would be mutually invited as observers at laboratory inspections.
   e. Provisions should be made for comparative testing whenever possible.
3. Context and consequences of an agreement:

   The agreement should specify the binding consequences which flow from it. Such consequences could include a provision that one party will recognize the test results or the laboratory accreditation system of the other party as equivalent to its own test results or system.

The authority for the working group to proceed with the work it recommended and to report on such further work at the ILAC/82 meeting in Tokyo next October, was approved by ILAC/81.

Scope of the "OECD Principles of GLP"

I believe that it is now appropriate to briefly summarize the issues that were addressed by the Expert Group.

In general, good laboratory practice is concerned with the process and conditions by which laboratory studies are carried out. Issues discussed in the "OECD Principles of GLP" document include:

- scope and purpose;
- terminology (definitions);
- health and safety precautions;
- test substance characterization, including stability testing as well as handling, storage, and disposal procedures;
- reagents and solutions;
- test facility organization;
- personnel training and experience;
- quality assurance programs;
- test facilities;
- equipment;
- standard operating procedures;
- performance of the study including study plan, conduct, record keeping, reporting of study results, and storage and retrieval of records;
- retention of records; and
- test system and test facility waste disposal.

The issues relating to (1) health and safety precautions and (2) test system and test facility waste disposal are relatively new issues that have not been widely discussed in previous GLP documents. The health and safety aspects have generally been a part of national legislation dealing with worker safety. Waste disposal considerations with respect to the test facility have been introduced into the OECD GLP document because the document addresses GLP concerns for health as well as environmental testing. Both of these types of testing have disposal problems associated with sizeable quantities of test system and test substance waste that may be toxic. As we continue to assess the potential hazards of chemicals, the handling and disposal issues will be brought into even sharper focus as a GLP concern.

Implementation of National GLP Programs in the International Framework

On May 12, 1981, on the proposal of the high level meeting of the OECD Chemicals Group which was endorsed by the Environmental Committee, the OECD Council adopted the "Decision Concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final)]." Under the overall objective of internationally harmonizing practices and procedures in chemicals control, the OECD council determined:

> "that data generated in the testing of chemicals in an OECD country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of man and the environment."

IMPLEMENTATION OF GOOD LABORATORY PRACTICE: INTERNATIONAL CONSIDERATIONS

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ABSTRACT - One of the first actions taken by the Organization for Economic Cooperation and Development (OECD) in the area of toxic substances was to develop an agreement on good laboratory practices (GLP). A group of experts met and agreed that in order to enhance the mutual acceptance of test data among countries and avoid nontariff barriers to trade, the countries must harmonize and implement the utilization of test guidelines, OECD Principles of GLP, and have in place an internationally harmonized, national GLP compliance program. The group of experts has met for 3 years and will present their final recommendations to the OECD Management Committee in December 1981.

In April 1978, representatives of 16 member countries of the Organization for Economic Cooperation and Development (OECD) and 6 international organizations met in Stockholm to discuss international issues related to the control of toxic substances. Good Laboratory Practice (GLP) was identified by these members as a priority issue which should require international attention. As a result of these discussions, a recommendation to the OECD resulted in an OECD Council Decision [C78 127(Final) (effective October 1978], indicating a broad consensus among OECD member countries that an international agreement on GLP should be a high priority goal. As a result of this decision, an OECD expert group was established under the leadership of the United States. This expert group was charged with the responsibility to develop a platform for international discussion and agreement on the principles of international GLP and issues relating to the implementation of national GLP compliance in the international framework. The recommendations of this expert group would form the basis for high level discussions within the framework of the OECD.

Recommendations of the Expert Group

During the past 3 years of the expert group's mandate, 74 experts from 17 countries including the Commission of the European Communities participated in this OECD expert group activity. The work of the group was divided into two phases. During the first phase, the expert group developed an "OECD Principles of Good Laboratory Practice" document. This document was presented as a recommendation to the OECD Chemicals Group at their high level meeting in the spring of 1980. The document was well received at the high level meeting and has subsequently been approved by the OECD Council in May, 1981, with the recommendation that it be provisionally implemented in member countries.

This concept of mutual acceptance of data in Member countries is intended to increase the confidence among OECD member countries in the reliability of test data generated in a foreign country. As more countries pass legislation to control chemical substances, governmental authorities will receive substantial quantities of test data from national and international laboratories for assessing the potential hazard these chemicals may pose to human health and the environment. As these test data are developed, emphasis should be given to the development of quality assurance procedures that will assure that data are developed under optimum good laboratory practice conditions. In order to foster the mutual acceptance of data, there is a need to establish an effective national GLP compliance program along with the application of the OECD Principles of GLP and the use of internationally accepted test guidelines. Acceptance and implementation of these three basic elements should foster the realization of the mutual acceptance concept. Attainment of this goal could lead to the elimination of duplicative testing, thereby reducing the burdens of cost and time imposed upon the international chemical trade. Reciprocal acceptance of test data internationally could contribute substantially to international trade and avoid possible nontariff barriers to trade.

With the mutual acceptance of data goals firmly in mind, the OECD expert group on GLP took on the challenges of defining the elements necessary to identify and harmonize national GLP compliance programs in the international framework during the second phase of the expert group's work. They addressed the issues involved in implementing the "OECD Principles of GLP" at both the national and international levels.

The expert group agreed that to enhance the mutual acceptance of test data among countries and avoid nontariff barriers to trade, countries must harmonize and implement the utilization of test guidelines, OECD Principles of GLP, and have in place an internationally harmonized, national GLP compliance program.

With respect to national issues, the expert group identified and emphasized that:

1. National governments should follow the OECD Principles of GLP.
2. National governments have the responsibility to implement a GLP compliance program, including provisions for taking action in cases of noncompliance.
3. National programs should monitor compliance with the OECD Principles of GLP through Laboratroy inspections and study audits.
4. National GLP compliance programs should provide for conducting inspections and study audits with sufficient frequency to enhance the assurance that the laboratory is maintaining its GLP compliance, status. In general, a 2-4 year frequency is recommended depending upon the type of testing being carried out by the laboratory.
5. National GLP compliance programs should focus attention to the use of qualified and properly trained personnel to carry out the inspections and study audits.

The expert group addressed several international issues relating to recognition and cooperation. Their final report provided the following statements and recommendations:

1. The establishment of effective national GLP compliance programs which are intended to assure the application of the OECD Principles of GLP and the use of the OECD Test Guidelines together form the basis for mutual acceptance of test data among OECD member countries.
2. An international mechanism needs to be established for recognizing the comparability of each national GLP compliance program with those of other OECD member countries.
3. It is recommended that a "notification" system involving the OECD council through which an OECD member country can declare that it has in place the three basic elements for mutual acceptance of data as specified above.
4. Regular and complete communication among national authorities regarding GLP compliance matters is recommended. Provisions are recommended for dealing the the receipt of "questioned" data from foreign laboratories and with the administrative handling of these sensitive issues.
5. An International GLP Forum is recommended as a communication vehicle to share technical and administrative matters in dealing with GLP implementation in and between OECD member countries.

OECD Guidelines for National GLP Inspections and Study Audits

As part of an effective national GLP compliance program, the expert group believed that there is also a need to harmonize with respect to how laboratory inspections and study audits are carried out in each member country. The expert group developed a guidance document for use by national authorities including national inspectors in performing GLP inspections and study audits. The expert group recommended that this guidance document should be accepted for use in all OECD member countries. It was the expert group's opinion that the utilization of these guidelines would enhance the confidence among member countries that inspections and study audits would be carried out in a comparable manner. The expert group also recommended that this document be reviewed periodically to assure that it properly addessses all concerns. Finally, the expert group recommended that this updating function be one of the activities of the International GLP Forum.

Disposition of the Expert Group's Final Report

It is important to note that the recommendations of the expert group set forth above have not yet undergone national review, or been presented to the OECD council. In early December 1981, the chairman of the expert group will formally present the final recommendations cited above to the OECD Management Committee. It is anticipated that the management Committee will provide the final report to all OECD member countries for national review and comment. These comments will then be formulated into positions by each national authority for presentation to the next high level meeting of the OECD Chemicals Group which is tentatively planning to meet in November/December 1982. Recommendations will then be formulated for OECD Council recommendations and/or decisions which will probably be made in the spring or early summer of 1983.

Conclusion

In conclusion, I have attempted to outline several aspects in developing an international approach to the mutual acceptance of test data through the utilization of internationally harmonized test guidelines and the implementation of the OECD Principles of GLP. To foster the international acceptability of these principles and procedures, national GLP compliance programs should be established incorporating the basic elements of laboratory inspection and study audits. To further the acceptance of internationally developed data, and to assure receiving countries that the data were developed and monitored through internationally harmonized procedures, it was recommended that countries utilize the OECD Guidelines for National GLP Inspections and Study Audits.

The availability of copies of the final report of the OECD expert group on GLP will be announced in early 1982. We would welcome all interested parties to provide their comments to our U.S. Delegation to the OECD Management Committee.

As Chairman of the OECD expert group on GLP, I would like to express my appreciation to all members of the expert group who provided their expertise and guidance during the development of the various documents contributing to the expert group's final report. In particular, I would like to thank the members of the U.S. Delegation: Mr. Ernie Brisson and Dr. Paul Lepore of FDA, Mr. Terrell Hunt, Dr. Art Stern, Dr. Richard Tucker, Dr. Larry Turner, and Dr. Diana Reisa of EPA; Mr. Don McCollister of Dow Chemical Co.; and Dr. Fred Freeburg of Proctor and Gamble .

I would now welcome any questions you may have concerning the final report of the OECD expert group on GLP.

RECOGNITION OF ACCREDITING AGENCIES
STATE OF THE ART

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ABSTRACT - A U. S. Department of Education Program is presented as representing the state of the art for recognition of accrediting agencies. The program's history, scope, administrative structure and procedures are discussed with special attention given to questions and issues that may bear upon considerations for establishing a similar program for recognition of laboratory accrediting agencies.

INTRODUCTION

The subject of this session deals with mechanisms for recognizing laboratory accreditation systems. My responsibility is to present a state-of-the-art paper on programs for recognizing accreditation organizations--not necessarily confined to programs for testing laboratories.

To my knowledge there is no generally accepted standard for recognizing accreditation programs; thus I have no benchmark against which to assess the "art." Alternatively, I have sought to describe a program as mature and broadly based as I could find. Such a program is the Department of Education's Program for Nationally Recognized Accrediting Agencies and Associations, and State Approval Agencies (referred to in this paper as Education's National Recognition Program).

A review of the literature concerning this program indicates that it:
- is called upon to serve national and international needs;
- accommodates private sector interests and government interests at the federal and state levels;
- has well defined policy, structure, criteria, and procedures evolved over several decades;
- has been exposed to the kinds of issues likely to stress any significant accreditation endeavor;
- enjoys the active support of varied interests; and,
- serves a sizeable constituency, varied in their interests and character.

The program area relates to educational institutions and programs, but I believe that the program is of a kind similar to that which might serve a system for recognizing agencies that accredit testing laboratories.

OVERVIEW

Nature and Function of Educational Accreditation

Postsecondary education developed in the U.S. without a centralized authority and with only limited and varying degrees of control by the states. Accreditation, providing voluntary peer evaluation of educational institutions and programs, became the primary means of encouraging quality in education. Private associations of educators and others having professional interest continue to be relied upon as the source for criteria and procedures for evaluating the quality of education. Presently the functions of education accreditation are stated to be:

1. Certifying that an institution has met established standards;
2. Assisting prospective students in identifying acceptable institutions;
3. Assisting institutions in determining the acceptability of transfer credit;
4. Helping to identify institutions and programs for the investment of public and private funds;
5. Protecting an institution against harmful internal and external pressures;
6. Creating goals for self-improvement of weaker programs and stimulating a general raising of standards among educational institutions;
7. Involving the faculty and staff comprehensively in institutional evaluation and planning;
8. Establishing criteria for professional certification, licensure, and for upgrading courses offering such preparation; and,
9. Providing one of several considerations used as a basis for determining eligibility for Federal assistance.[1]

Types of Educational Accreditation

Two types of educational accreditation are practiced. Institutional accrediting associations provide for evaluation and recognition of entire institutions, assuring that each of its parts adequately meets the institution's goals. This does not necessarily mean that all parts perform at the same level of quality. Universities, liberal arts colleges, junior colleges, and broad-based vocational schools seek such accreditation. The educational institutions may be non-profit or proprietary in nature.

Specialized or program accrediting agencies provide evaluation and recognition of a unit of education, usually a curriculum or a technical discipline. The unit may be a college, department or a program within such an entity, or the unit may be an entire specialized institute such as a professional school or a specialized vocational school. Some specialized accrediting agencies may accredit educational programs within non-educational environments, such as nurse training programs in hospitals.

Most of the institutional accrediting associations and several of the specialized accrediting agencies provide a preaccreditation status to educational institutions or programs working to achieve accreditation status.

National Recognition--History and Current Status

The need for national recognition of accrediting agencies in education was first reflected by actions taken by the U.S. Office of Education and also by private sector groups in the late forties. From 1870, the Office published a directory of U.S. universities, colleges, and technical schools, relying upon self-assertions of the schools for the necessary data. In 1911, an attempted revision of the directory was made, at the request of the Association of American Universities (AAU), to rate the schools on the basis of the performance of their alumni in graduate studies. Such quality ratings, however, were not thought to be an appropriate function of government. Thereafter, the U.S. directory listed schools, and their ratings, as supplied by private accrediting groups--the AAU and other accrediting agencies as they developed. The proliferation of accrediting agencies seeking publication of their listings in the directory prompted the Office of Education to publish in 1948, "Criteria for Recognition of Accrediting Agencies." The criteria were developed with the assistance of the American Council on Education.

Private sector bodies were also acting. The post World War II era witnessed expanded efforts of colleges and universities to recruit students on a national basis. This developed the need for national recognition of their accreditation status which was usually granted by regional institutional accrediting associations. In 1949, the six regional groups organized a coordinating association, the Federation of Regional Accrediting Commissions of Higher Education (FRACHE). Its purpose was to promote cooperation and harmonization of accreditation standards. In the same year, the National Commission on Accrediting (NCA) was established, led by educators such as university presidents who were concerned about the rising costs and bother resulting from increasing demands for specialized accreditation.

In the years prior to 1950, the proliferation of specialized accrediting agencies was fired by state trends to license professional practice and by national professional societies and deans of professional schools acting to respond to these demands. The NCA's aim was to discourage this growth and to bring specialized accreditation under institutional accrediting authority. Prior to 1950, accreditation interest, both private and Federal, was directed primarily toward collegiate, nonprofit institutions. Except in response to state licensure requirements, accreditation practice was motivated by the needs of educators and their institutions. The Federal mission, limited to providing national recognition to schools (and their accrediting agencies) to serve public information needs, was to undergo a transformation beginning in the fifties.

The Veterans' Readjustment Assistance Act of 1952 (the GI bill for Korean War veterans) and the National Defense Education Act of 1958 provided financial assistance to students attending "eligible" institutions or educational programs. Eligibility required accreditation by an agency nationally recognized by the Commissioner of Education. As a practical matter, the need to be nationally recognized became a necessity for most educational accrediting agencies. Immediately following passage of the 1952 act, the existing criteria for national recognition of accrediting agencies, established in 1948, were revised. The 1952 criteria, developed with the assistance of an advisory group of educators drawn mainly from the National Commission on Accrediting, contained requirements deemed more appropriate for serving the public need in addition to the needs of educators and schools.

The sixties saw the passage of several educational statutes that tied eligibility of postsecondary schools to receive Federal funds to accreditation by nationally recognized accrediting agencies. Included among these statutes were:

- the Health Professions Acts of 1963, 1966, and 1968;
- the Nurse Training Act of 1964;
- the National Vocational Student Loan Act of 1965; and,
- the State Technical Services Act of 1965.

The effect of these statutes was to make larger numbers and kinds of educational programs, and institutions of more varied character, eligible for federal funding--all dependent upon their being accredited by nationally recognized agencies. Vocational and nondegree programs of postsecondary education, proprietary schools and some noneducational institutions joined collegiate programs and nonprofit institutes seeking accreditation. The increasing need and demand for accreditation exerted pressures upon existing recognized accrediting agencies to expand their scope, modify their accreditation criteria and increase their services. To the extent that the established accreditation agencies wouldn't or couldn't fill the void, new accreditation agencies quickly formed to serve the need and, thereafter, applied to Education's National Recognition Program. It is reported that in 1968, the program processed twelve applications from accreditation agencies seeking initial recognition.[2]

By 1968 an organizational entity was established in the Office of Education to handle the increased workload--the Accreditation and Institutional Eligibility Office. In the years since its formation this office has developed policy and procedures for administration of the program, developed new sets of criteria and procedures for recognition of state agencies for approval of nurse education, and postsecondary vocational education. The office revised the 1952 criteria for nationally recognized accreditation agencies and associations in 1969 and, most recently, in 1974. A large portion of the office's effort has been committed to the processing of a continuing flow of petitions from accrediting agencies for initial recognition, continuing recognition, or for extension in scope of their accrediting activities.

Currently, it is stated, to serve, "... various Federal purposes, the U.S. Secretary of Education is required by statute to publish a list of nationally recognized accrediting agencies and associations which the Secretary determines to be reliable authorities as to the quality or training offered by educational institutions and programs."[3] By statute, he, "... is required to publish lists of State agencies for approval of public postsecondary vocational education, and for approval of nurse education, ...[4] Most postsecondary institutions attain eligibility for Federal funds by holding accredited or preaccredited status with one of the accrediting bodies recognized by the Secretary of Education, in addition to fulfilling other eligibility requirements. In some legislation, provision is made for special qualifying steps that may be taken as alternatives to the normal accreditation process."[3]

It is important to note that, "... accrediting agencies which are recognized by the Secretary have no legal control over educational institutions or programs. They promulgate standards of quality or criteria of institutional excellence and approve or admit to membership those institutions that meet the standards or criteria."[3]

Overview Summary and Issues

The U.S. Secretary of Education is required by various federal statutes dating from 1952 to recognize and list accrediting agencies for postsecondary education. Prior to this legislation the U.S. government already had, in cooperation with educators and other interests in the private sector, established a program for recognition of accrediting agencies in postsecondary education. Historically the early development of a U.S. program for recognizing accrediting agencies in education appears to derive from three events.

1. In 1870 the U.S. Bureau of Education decided that the public, particularly educators and their prospective students, would be served by a national directory of postsecondary educational institutes. Universities, colleges and technical schools were listed on the basis of their self-assertions regarding the nature of training that they provided. No form of evaluation or accreditation was involved.

2. In 1911 educators suggested that educational institutions meet quality standards in order to be listed in the national directory. The government declined this request, believing that establishing the quality of postsecondary education is the responsibility of educators in the private sector. However, the government did agree to limit the listing of educational institutions in the national directory to those accredited by private sector agencies. Such accrediting agencies, and their listings of educational institutions, were accepted on a non-selective basis. Initially, only a few regional accrediting agencies developed from peer groups of educators. Their objective was institutional accreditation, that is, accrediting universities, colleges, and technical schools in their entirety.

3. By 1948 the proliferation of accrediting agencies created a need to modify the 1911 plan. Action by states developing licensure and certification requirements for professions and vocations, activities of national professional societies and efforts of deans of professional and vocational departments created a demand for specialized accreditation -- the accreditation of specific curricula or units of education rather than entire education institutions. The early cadre of regional accreditors, favoring institutional accreditation, resisted demands for specialized accreditation and thereby fostered the growth of specialized accredited agencies. The growing numbers of accrediting agencies made it necessary by 1948 to establish means to choose from those accrediting agencies seeking publications of their listings in the national directory. An informal government program for recognition of accrediting agencies was born in 1948 when the Office of Education, with assistance of the American Council on Education, published its, "Criteria for Recognition of Accrediting Agencies."

Legislation of the fifties and sixties, authorizing the use of the program for determining the eligibility of educational institutes and programs to receive federal funds, had several impacts. The program's scope, previously covering private accrediting agencies for collegiate and professional education, was expanded to match the scope of the legislation. The program was required to extend its recognition to state approval agencies and to private accrediting agencies for vocational and nondegree postsecondary educational programs and to accrediting agencies for proprietary schools and for certain noneducational institutions, such as hospital nursing schools. In 1968 alone, the program processed twelve applications from accrediting agencies seeking their initial recognition. With the increase in scope and the fact that the program had become an important element in the distribution of major federal funds, the nature and interest of the program's constituency gradually expanded together with the functions of accreditation. The original constituency of collegiate and professional educators representing non-profit institutions and programs expanded to include congressional, state, vocational and general public interest. The functions of accreditation expanded from those related to ascertaining quality of education to include those pertaining to social, public, and other issues. The program, conducted initially on an informal basis with occasional help and advice of the original constituency of collegiate and professional accreditors, evolved into a formal program with staff and an advisory committee representing the public interest in postsecondary education.

Considering the development of Education's National Recognition Program raises certain questions regarding the establishment of a similar program for recognition of accrediting agencies for testing laboratories. The Department of Education, the singular Federal authority for education, depends wholly upon private and state accrediting agencies and has reason to establish a program and criteria for recognition of such agencies. In turn, the accrediting agencies have reason to seek recognition as, thereby, their accredited members can comply with Federal rules and funding eligibility requirements. Thus there is centralization of Federal interest and the cohesiveness of mutual need between Education's National Recognition Program and its users.

The testing laboratory scene is somewhat different. There is little effective centralization of interest or authority for accreditation in the federal, state or private communities. The National Voluntary Laboratory Accreditation Program (NVLAP) has provided a mechanism for focusing such interest but, to date, has had only limited success. Laboratory accreditation programs tend to be established to serve particular limited interests rather than the overall national need. If NVLAP is to change its present role to that of offering recognition to accrediting agencies, a critical question should be answered. Are there compelling reasons, similar to those in the education field, for accrediting agencies for testing laboratories to seek recognition from such a program if it were established? If such compelling reasons do not exist what needs to be done to create a more favorable climate?

EDUCATION'S NATIONAL RECOGNITION PROGRAM

Scope of the Program

Specialized accrediting agencies and institutional accrediting associations operating on a voluntary basis are recognized by the Secretary of Education in accordance with procedures and criteria contained in Title 45, Code of Federal Regulations, Part 149, Subpart A, "Criteria for Nationally Recognized Accrediting Agencies and Associations."[5]

State agencies acting to approve public postsecondary vocational education for the purpose of determining eligibility for Federal assistance are recognized by the Secretary in accordance with procedures and criteria contained in Title 45, Code of Federal Regulations, Part 149, Subpart B, "Criteria for State Agencies."[6]

State agencies acting to approve schools and programs in nursing education are recognized by the Secretary in accordance with informal procedures and criteria published in the Federal Register, January 16, 1969.

Under these rules, approximately 80 accrediting bodies and 20 state approval agencies presently are granted national recognition. As a group these nationally recognized organizations accredit or approve about 3000 universities, colleges and schools and about 8000 specialized programs of postsecondary education. As a result of this accreditation, this vast number of educational institutes and programs fulfills a major part of the eligibility requirements for Federal funding assistance.

Postsecondary schools and programs accredited by these nationally recognized agencies enjoy national recognition beyond that related to funding assistance. A recent survey indicates that 23 federal agencies use the program's listing for determining compliance required by 28 various statutory provisions.[7]

In regard to international scope, the program does not grant recognition to foreign accreditation bodies nor does it list accredited institutions and programs located outside the fifty states and U.S. territories. Certain Federal statutes allow financial assistance to students attending foreign schools. To date, the eligibility of such schools is determined on a case by case informal basis. However, the program has been reviewing draft regulations for foreign medical school comparability.[8]

Administrative Structure

Administration of Education's National Recognition Program is provided by three entities: the Assistant Secretary for Postsecondary Education, the National Advisory Committee on Accreditation and Institutional Eligibility, and the Division of Eligibility and Agency Evaluation.

The Assistant Secretary for Postsecondary Education has been delegated authority by the Secretary of Education to make the final decision regarding recognition or renewal of recognition of an accrediting agency or association.[9]

The National Advisory Committee on Accreditation and Institutional Eligibility established by statute in 1980, is composed of 15 persons appointed to 3 year terms by the Secretary of Education. Its membership is selected to represent the educational and student communities, state departments of education, professional associations and the general public. The Committee assists the Secretary in the, "... performance of eligibility determining duties imposed by ... the Veterans' Readjustment Assistance Act of 1952, and subsequent legislation. It also serves to advise the Secretary on broader policy matters and specific issues relating to accreditation and institutional eligibility for Federal funding." The Committee's specifically mandated functions include:

- review of current and future policies for the recognition and designation of accrediting agencies, associations and state agencies, and recommendation of desirable changes in criteria and procedures;
- development and recommendation to the Secretary of criteria and procedures for recognition of accrediting agencies, association, and state agencies in accordance with statutory provisions, Executive Orders or interagency agreements;
- review of all applicant accrediting agencies, associations and state agencies which meet the criteria and recommendation to the Secretary regarding their national recognition;
- review and advise the Secretary on current and future policy relating to institutional eligibility;
- review of current legislation in the area of accreditation and institutional eligibility and suggestion to the Secretary of needed changes;
- advising the Secretary concerning relations with accrediting agencies or associations, or other approval bodies as the Secretary may request;
- development and recommendation to the Secretary of standards and criteria for specific categories of educational institutes which have no accreditation route by which to establish eligibility;

- maintaining a continuous review of administrative practice, procedure, and judgments relating to accreditation and institutional eligibility and advising the Secretary of needed changes;

- making each year an annual report of its activities, findings and recommendations.[10]

Prior to its becoming a statutory committee, established by public law, the Committee functioned from 1968 as an advisory committee in accordance with the provisions of the Federal Advisory Committee Act. Under its last charter (1978) the membership, composition and functions were identical to those specified for its new statutory form. In 1978 the estimated costs of Committee operations including compensation ($100 per day) and travel costs were $75,000. Estimated staff support was $55,000. It is noted that the first advisory committee, chartered in 1968, did not include representation from the general public or from the student community. It did include representation from the accrediting community who were primary contributors until 1971. Thereafter, the accreditation community was not represented on the committee.[11]

The Division of Eligibility and Agency Evaluation (DEAE) was established in 1976. Previously its work had been performed by a staff office called the Accreditation and Institutional Eligibility Staff, formed in 1968.[12] The Division's functions are stated to be:

- administration of the processes whereby accrediting associations secure initial and renewed recognition and whereby institutions are determined eligible for funding;

- continuous review of issues, policies, and procedures relative to accreditation and eligibility;

- interpretation and dissemination of policy relative to accreditation and eligibility for funding issues;

- support for the Advisory Committee on Accreditation and Institutional Eligibility;

- liaison with accrediting associations and consultative services to institutions, associations, Federal agencies, and Congress regarding accreditation and eligibility for funding issues; and,

- conduct and stimulation of appropriate research.[13]

The Division is presently reported to have a director, four staff members, plus clerical support. I suspect, given the present environment, that this staffing allotment is pared to the bone. It is noted that the 1978 charter authorizing the previous advisory committee estimated three man-years for support of the committee, only one of the functions of the Division.

Although not an official part of the administrative structure, the program's literature notes two nongovernment organizations that undoubtedly provide significant contributions due to their involvement with postsecondary educational accreditation, namely, the Council on Postsecondary Accreditation and the Council of Specialized Accrediting Agencies.[14]

The Council of Specialized Accrediting Agencies was established in 1973. Its purpose is, "... to strengthen the effectiveness and quality of postsecondary professional and specialized education through accreditation...." The Council collaborates, "... with other postsecondary accrediting agencies on behalf of the specialized organizations."

The Council on Postsecondary Accreditation derived in 1975 from consolidation of the National Commission on Accrediting and the Federation of Regional Accrediting Commissions of Higher Education. As noted in the Overview section of this paper, these two organizations were established in 1949 to harmonize regional accreditation standards and to govern the growth of specialized accreditation. According to Makau[15] the consolidation of these organizations into the Council on Postsecondary Accreditation (COPA) was meant to restrain, "... Federal intrusion into the affairs of accrediting agencies and ... discourage their fragmentation."*

The Council's role is to, "... foster and facilitate the role of accrediting agencies in promoting and insuring the quality and diversity of American postsecondary education. The Council recognizes, coordinates, and periodically reviews the work of its member accrediting agencies, determines the appropriateness of existing or proposed accrediting activities and performs other related functions."

The Recognition Process

The process of recognition or renewal of recognition of applicant accrediting agencies involves five stages: development of the petition, submission of the petition; analysis; hearing; and the final decision.[17]

Development of the Petition

An applicant accrediting agency develops a narrative statement showing how it complies with the criteria for recognition. Clearly referenced supportive documentation is attached including: standards and procedures; independent financial audit statement; list of schools or programs accredited; on-site visit guidance material; self-evaluation guidelines; and samples of completed self-evaluations and site visit reports.

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*Regarding "Federal intrusion" it is of interest to note that in 1968 the Commissioner of Education issued a public statement which read in part, "It is the policy of the Office of Education generally to support and encourage the various recognized voluntary accrediting associations in their respective activities, and to endorse their role as the primary agents in the development and maintainance of educational standards in the United States. The Office also supports and encourages the National Commission on Accrediting in its role as a national coordinator and spokesman for voluntary accreditation."[16]

Submission of the Petition
The petition, with seven copies is submitted to the Division of Eligibility and Agency Evaluation at least three months before its scheduled review by the Advisory Committee.

Analysis
The Division staff analyzes the petition. Staff or consultants observe an on-site visit and attend the agency's decision-making procedure. Staff may visit the agency's administrative office, review operations and facilities and interview agency personnel. Staff may also conduct interviews or surveys of other persons and organizations to determine that the agency complies with the criteria. A written analysis with appendices (staff observations, surveys, etc.) is forwarded to the Advisory Committee, to the applicant agency and interested third parties.

Hearing
Usually, an agency's petition is assigned to one of two subcommittees of the Advisory Committee. Each member of the subcommittee is provided a copy of the agency's petition. Each member of the full Advisory Committee receives a copy of the Division's analysis. The petitioning agency, the Division staff, and requesting third parties are invited to make oral presentations to the responsible subcommittee. The subcommittee reports its findings and recommendations to the full Committee which adopts final recommendations that are forwarded to the Assistant Secretary for Postsecondary Education. The Advisory Committee meets approximately four times a year to consider petitions. Meetings are public and a transcript of the proceedings is taken.

Final Decision
The Assistant Secretary may grant recognition or renewal for a period up to four years depending upon the degree of compliance with the criteria. The decision will include a statement of the scope of the agency's recognized activities.* The Assistant Secretary may also: defer action for further study; deny initial recognition; or, request a recognized agency applying for renewal to show cause as to why it should not be removed from recognized status. Listings of recognized accrediting agencies are published periodically in the Federal Register and in appropriate brochures.

Criteria for Recognition of Accrediting Agencies

As indicated in the Overview section of this paper, criteria for recognition of accrediting agencies, first published in 1948, were revised in 1952, 1969, and most recently in 1974. Six requirements imposed upon accrediting agencies by the 1948 criteria have increased to 47 requirements contained in the 1974 revision.

Some of this increase derived from increased sophistication in the accreditation art. Whereas the 1948 version required agencies to have published listings and criteria, the 1974 version specifies an agency's publications must include its purposes and objectives, its evaluation standards, its procedures for determining accreditation status, its appeal procedures and identification of its key personnel, ownership and control. The 1974 criteria also require the agency to have written procedures for review of complaints and written guidelines for on-site examinations for use by both the school being examined and the visiting team.

The 1948 criteria merely required an agency to provide on-site visits and periodic reevaluations. The 1974 version expands upon these requirements, specifying that the agency must also collect data from accreditation applicants demonstrating on-going evaluation programs. The recent criteria also specify that an agency, as part of its accreditation practice, must require a school or program to submit a self-analysis involving staff, faculty, student and other constituent participation.

Although sophistication in the accrediting art generally caused an increase in criteria for recognition of accrediting agencies, one exception is noted. The first criteria in 1948 included as one of its elements several specific requirements that an accrediting agency needed to impose upon schools or educational programs. In other words, criteria for recognition of accrediting agencies embodied criteria for the accreditation of schools. Later versions of the criteria ('52, '69, '74) are, in general, devoid of such requirements. This is consistent with traditional government policy for postsecondary education--that educational standards for postsecondary education are the province of the private sector and the states and that accreditation standards for schools are a matter for educators and their accrediting agencies to resolve.

Other criteria contained in the 1974 version reflect an evolution of public involvement and the concerns of a growing educational community. The numbers and types of postsecondary schools and programs increased tremendously since 1950. It has been stated that the growth rate exceeds that of any industry, that per capita expenditure on education, in constant dollars, increased over ten fold in a recent 25 year period.[18]

As public interest and involvement grew, the means of formulation of the criteria and the criteria themselves took on new aspects. Prior to the 1970's, versions of the criteria were developed primarily with assistance and advice of the traditional constituency of educators and accrediting bodies. The 1974 revision involved the development of several working drafts each distributed for review to all recognized accrediting agencies and their federations, to educational institutions, student groups and state governments. The process took three years.[19] The criteria that resulted included aspects that related to accountability, integrity and the responsiveness of accrediting agencies to public issues.

In regard to accountability the 1974 criteria require an agency to submit an independent financial audit showing it to have financial plans and resources to carry out its operations in a timely and effective manner.

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*Recognized agencies seeking extension of scope may petition for such extension at any time or include such extension as an integral part of their renewal petition.

Also, the agency must show that it reviews its policies, procedures and standards to assure their relevancy and reflect the needs of students. Agencies must also act to assure that references to its accreditations clearly specify the areas and levels for which accreditation is issued.

The integrity of accrediting agencies is addressed. Agencies must not charge fees exceeding reasonable costs of sustaining and improving its accreditation process, and it must accredit only schools and programs that meet it standards. The agency's procedures must guard against conflict of interest and it must perform no function inconsistent with maintaining its independent judgment.

The 1974 criteria require responsiveness to public concerns. The agency's personnel, including consultants and visiting teams, must be qualified and selected in a nondiscriminatory manner. Its accreditation practice must encourage experimental and innovative educational programs and must take into account the rights, responsibilities and interest of students, educators, professions, vocations and the general public. The agency must foster ethical practices in schools and educational programs, including equitable student refunds and nondiscriminatory practices.

Increasing litigation also had its effect. By the late 1960's accrediting agencies, nationally recognized under the 1952 criteria were being taken to court for refusing to accredit. For instance, in 1969 a U.S. District Court ruled against an accrediting agency whose accreditation criteria required a school to be nonprofit, finding that:

- the defendant, acting in combination with its federation, had unreasonably restrained trade;
- the defendant was engaged in a quasi governmental function subject to Constitutional restraint (due process); and,
- refusal to accredit because of corporate form was arbitrary, discriminatory, and unreasonable.[20]

A U.S. Court of Appeals later reversed this decision, but mainly for exceptional and technical reasons that might not apply in other cases.[21] The Supreme Court refused a request to hear the case, leaving open a general resolution of the issues.

"Due process" requirements were introduced in the 1969 revision of the criteria and were expanded upon in the 1974 version. These criteria relate to proposing and revising standards, on-site visits, evaluation procedures, adverse accreditation actions, and appeals. Such criteria also require an agency to provide for a balance of affected interests and for public input into its policy and decision making bodies.

The foregoing comments pertain to the evolution of criteria for nationally recognized accrediting agencies--generally private organizations operating voluntary accreditation programs for public and private postsecondary educational enterprises. The use of accreditation as a basis for determining eligibility for federal funding generated interests of the states in approving postsecondary educational institutes and programs. As a result, the Health Manpower Act of 1968 and the 1972 Mondale Amendment to the Higher Education Act of 1965 authorized the Commissioner of Education to extend recognition to state agencies for approving nurse education and public postsecondary vocational education in their respective states. Criteria for recognition of state agencies for approval of nurse education were developed with the assistance of the U.S. Public Health Service, several state boards of nurse examiners, the American Nurses Association and the Council of State Boards of Nursing. The criteria were published in 1969 and are still in effect.

Criteria for recognition of state agencies for approving vocational education were developed by a task force which distributed working drafts for review. Opinions of state government officials were given special emphasis. The criteria were published in 1974 as a companion part to the 1974 criteria for recognition of accrediting agencies and associations.

Questions and Issues

Questions arise regarding the appropriate scope of a program for recognition of accrediting agencies for testing laboratories. Accrediting agencies applying for recognition under Education's National Recognition Program are considered to provide a public service and are therefore required by the criteria to have governmental or quasi governmental character. Should a contemplated testing laboratory program be restricted in scope to those accrediting agencies serving a public need? Should the program provide recognition for foreign accrediting agencies?

An issue arises regarding the administrative structure of a recognition program for laboratory accrediting agencies. The policy and decision development body for Education's National Recognition Program, namely, the Advisory Committee, does not now include representation of the accrediting agency community--in its initial and earlier structure such interests were heavily represented. Presently, input from such constituency is received from recognized but unaffiliated outside councils, the Council of Specialized Accrediting Agencies and the Council on Post-secondary Accreditation. Should a recognition program for laboratory accrediting agencies contain accrediting agency representation on it policy and decision making bodies? Is there need for outside councils representing such interests?

Perhaps one of the most important issues concerns the nature of criteria that might be promulgated by a recognition program for laboratory accrediting agencies. Should such criteria be limited to those that assure that accrediting agencies adequately assess the technical and professional competence of laboratories; or should criteria also contain provisions related to public concerns such as accountability, integrity, due process, and responsiveness to public issues? The criteria of Education's National Recognition Program evolved from one to the other as its public profile grew. Another question regarding criteria to be used by a recognition program for laboratory accrediting agencies is, "Should such criteria contain requirements that accrediting agencies must impose, or not impose, upon testing laboratories?" In the education field, federal policy is that such requirements are the concern and responsibility of the private sector and the states, so criteria of Education's National Recognition Program are generally devoid of requirements that accrediting agencies must impose upon educational programs. However, as shown, criteria imposed by accrediting agencies can be subject to judicial review. Furthermore, in the testing field the Federal Government has not divorced itself from establishing standards for testing or evaluation of testing practice.

PROLIFERATION OF ACCREDITING AGENCIES

The history of Education's National Recognition Program has witnessed a continuing expansion of the numbers of education accrediting agencies, as indicated in the following table.

Year	Number of Accrediting Agencies	Remarks
1928	5	No criteria for accrediting agencies
1934	14	
1944	22	
		Simple criteria introduced in 1948. Accreditation coupled to eligibility for funding assistance, 1952
1966	29	
1967	32	
1972	47	Relatively complex criteria in 1974
1978	74	
1981	78	

This growth occurred despite the introduction of increasingly complex criteria for recognition of agencies and despite the intent of the program and national associations and federations to control such proliferation. For instance, the 1974 criteria require an agency to be national or regional in scope; to demonstrate its acceptance throughout the U.S. by educators, institutions, licensing bodies, practitioners and employers; and to have at least two years of experience as an accrediting agency. The preamble to the 1974 criteria notes that in view of the criteria it is unlikely that more than one agency will qualify for recognition in a defined geographical area or in a "defined field" of program specialization. The preamble further states that if more than one agency in a "defined field" seeks recognition, they will both be expected to demonstrate need for their activities and show that they do not unduly disrupt affected schools or programs.

The 1980 Directory lists nationally recognized accrediting agencies and associations, most of them providing specialized accreditation of professional or vocational education.[22] It is noted that the directory lists seventeen different accreditation programs in the health technology field alone. It appears that if sufficient interest and need is indicated, a "defined field" can be quite narrow in scope.

The proliferation of accrediting agencies undoubtedly was encouraged by the rapid growth of schools and educational programs and by Federal legislation that provided funding assistance for increasing numbers and types of schools and programs. There also appears to have been a hesitancy on the part of traditional accrediting agencies to accept new needs for professional and vocational accreditation programs. Established non-profit collegiate institutions and their institutional accrediting agencies were concerned that such extension of accreditation programs could impose unacceptable costs and inconvenience on their institutions. Their concerns may have been justified. The 1980 Directory indicates that Ohio State University is accredited by an institutional accrediting agency and by thirty specialized accrediting agencies, for programs ranging from architecture to veterinary medicine.[23]

It is difficult to say with assurance whether Education's National Recognition Program stimulated or discouraged the proliferation of accrediting agencies. If we assume that the same needs for accreditation had developed (that is, accreditation of 11,000 schools and programs), no one can say with certainty how this would have been achieved without the program. One does not know whether there would be a greater or lesser number of accrediting agencies. What can be done is to compare for a period of time the number of accrediting agencies granted recognition or renewal of recognition with the number of petitions for recognition or renewal processed in that time--the screening function. For the period 1974 to 1978, the program processed 200 applications for recognition or renewal.[24] The 1980 Directory indicates that 69 agencies were granted initial recognition and/or renewal of recognition during the same time period. Although this evaluation is subject to some error, it implies that about one-third of the applicant agencies qualified for national recognition in the period 1974-78.

Rules and criteria of Education's National Recognition Program act to discourage duplication of accreditation activity but do not appear to discourage fragmentation of such activity. For instance, rather than a single recognized accrediting agency for the health technology field, there are seventeen. In considering a recognition program for laboratory accrediting agencies, it may be appropriate to consider the following questions.

- To what extent should fragmentation be controlled?

- Education's National Recognition Program requires an applicant accrediting agency to demonstrate need and acceptance by affected constituency throughout the U.S. However, the program allows the applicant agency to define the field of specialization. It is likely that the narrower the field, the easier it is to demonstrate need and to align constituency support. Thus the program requirements may encourage fragmentation. Are there alternatives to an applicant accrediting agency defining the field of specialization? Can a recognition program for accrediting agencies place limits on the degree of specialization?

- Education's National Recognition Program minimizes the duplication of accrediting activity in the educational field only to the extent that it attracts all such accrediting activity to seek and obtain recognition under the program. Assuming that a recognition program for laboratory accrediting agencies would also seek to minimize duplication, its effectiveness will also depend upon its ability to attract all accrediting agencies. What enticements could a program for laboratory accrediting agencies offer that would encourage such agencies to seek recognition and to submit to the program's requirements for coordination?

GENERAL COMMENTS

An independent study on the reliability, validity and impact of the Program was recently contracted by the Department of Education.[26] The study team was assisted by coordinating and technical advisory committees whose membership included student, professional association, accreditation agency, faculty, and university administration representation. The study utilized input and opinions of accreditation agency directors and nonagency experts. The study concluded that:

- The criteria relate to important aspects for identifying accrediting agencies that adequately evaluate the quality of educational programs and institutions. Aspects considered most important were the development and maintenance of standards, the procedures for evaluating programs or schools, and the fairness and integrity of the accrediting process. Related requirements of the criteria, such as publication, clear definition, fair application and periodic review of standards were considered to be important requirements for accrediting agencies. Interestingly, evaluation of validity and reliability of their standards and correlation of the standards against the performance of program graduates were thought to be considerably less important.

- The criteria have been applied consistently. It was concluded that about two thirds of the characteristics of accrediting agencies used in rating their compliance with the criteria were reasonably open to observation. Characteristics of accrediting agencies difficult to observe related to the effectiveness, merit or quality of their activities.

- The recognition of accrediting agencies has been appropriate. Accreditation agencies granted recognition functioned better than agencies denied recognition in regard to important aspects, namely, the strength of their evaluation procedures and in the fairness and impartiality of their decisions.

- The program would be strengthened by providing more specific guidelines to accrediting agencies for meeting the criteria, particularly guidelines relating to the quality rather than the mere existance of procedures required by the criteria.

- Procedures of accrediting agencies have become more systematic, self-study and site visits have improved and standards have become stronger and better defined. Improvement of self-study procedures, complaint procedures and public representation on accrediting agencies' governing boards were attributed to the influence of the program. Criteria related to organization structure, integrity or concern for due process had not affected changes in accrediting agencies.

A final comment relates to the impact that government adminstrative practices can have on its programs. In early 1979, the Office of the Commissioner of Education submitted to the Program Office alternative criteria to serve as a focal point for further revision of the criteria. According to the program's advisory committee these alternative criteria would:

- restrict recognition of accrediting agencies to those solely serving funding eligibility purposes (eliminating those serving other Federal purposes);

- restrict recognition of accrediting agencies to those performing institutional accreditation;

- require a choice between accrediting agencies that serve overlapping functions;

- require agencies to demonstrate their national recognition prior to recognition by the program;

- eliminate requirements that an agency control its own budget, have external audits, and demonstrate the reasonableness of its fees;

- eliminate requirements on agencies for various accreditation procedures, guidelines for on-site visits, and the evaluation of the validity and reliability of their standards;

- eliminate many due process requirements;

- eliminate requirements that agencies foster ethical and nondiscriminatory practices;

- eliminate requirements that agencies encourage educational innovation;

- eliminate requirements that visiting teams include at least one non-staff or non-policymaking member;

- eliminate provisions insuring against conflict of interest and that an agency be autonomous in its actions and decisions;

- eliminate requirements on agencies for complaint procedures; and

- eliminate requirements for public participation in decision making processes and the taking into account the rights, responsibilities, and interests of affected constituencies.[27]

Quoting the Advisory Committee Report, "The release of these substantially different criteria generated considerable discussion." Paradoxically, it would seem that these alternative criteria would restrict the program solely to a public service function (determining eligibility of schools and programs for public funds) while, at the same time, eliminating criteria that assumably had been imposed upon accrediting agencies because they served a public service function.

An exchange of views between the Advisory Committee and the Commissioner's Office occurred thereafter. Convinced that a difference of opinion existed between the Committee and the Commissioner regarding their respective roles and functions, the Committee considered that resolution by Congressional action was merited. Thereafter, the Administration introduced legislation in July 1979 that would have, if enacted, removed accreditation as a means for determining eligibility for public funding. In August the Office of the Commissioner was vacated. The Advisory Committee, with essentially the same composition and functions became the National Advisory Committee on Accreditation and Institutional Eligibility, established by statute under the Educational Amendments Act of 1980.[28]

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PROPOSAL
TO TRANSFER THE CURRENT NVLAP SYSTEM INTO A SYSTEM FOR ACCREDITING PRIVATE ACCREDITATION SYSTEMS

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The presentation centers around the American Association for Laboratory Accreditation (AALA) proposal that the role of the National Voluntary Laboratory Accreditation Program (NVLAP) be changed from that of accrediting laboratories to one of being an accreditor of accreditation systems and the primary link between the laboratory accreditation community in the United States and the international laboratory accreditation community.

Laboratory accreditation is a concept whose time has come. Industry and consumers demand that laboratory test results are reliable and are produced efficiently and with consistency. To quote from the report prepared for the Department of Commerce (DOC) by C. W. Hyer, "Principal Aspects of U.S. Laboratory Accreditation Programs," "...whatever a testing laboratory's purpose or no matter who owns it, if a laboratory cannot perform competently and reliably, it would be better if that laboratory did not operate."

There has existed for more than a decade an urgent need for a national mechanism for accreditation of testing laboratories. Lack of such a mechanism is a disservice to industrial, commercial, professional and government purchasers of laboratory services who legitimately seek some formal recognition of a laboratory's competence.

The stated purpose of this workshop concerns itself with the present status and future direction of laboratory accreditation and the recommendation that NVLAP assume the role of accreditor of accreditation systems and provide the link with the international laboratory community.

This paper will address legal and policy guidelines either published or supported by the current administration which provide the impetus for the movement of laboratory accreditation to the private sector, will summarize criteria for standardizing and operating laboratory accreditation systems, and will conclude with basic recommendations to be included in a proposed regulation published by DOC as a result of this public hearing.

I submit that the argument "...if a laboratory cannot perform competently and reliably, it would be better if that laboratory did not operate," is the basic theme which underlies the increasing demand for better and more organized accreditation systems. Further, there has been an urgent need expressed both nationally and internationally for governmental programs to accredit laboratory accreditation systems. A large number of laboratory accreditation programs are in operation both nationally and internationally. The International Directory of Laboratory Accreditation Systems indicates that seventy laboratory accreditation systems are now operational within the United States.

To reinforce this argument, the administration recently published the Office of Management and Budget (OMB) Circular A-119, which states that the general policy of the Federal government will be to rely on voluntary standards, both domestic and international, with respect to Federal procurement; to participate in voluntary standards bodies when such participation is in the public interest and is compatible with agencies' missions, authorities, priorities and budget limitations; and, finally, to coordinate agency participation in voluntary standards bodies in order to increase the effectiveness of Federal agency representatives and to ensure that the views expressed by such representatives are in the public interest.

The new administration has recognized that services such as laboratory accreditation can be provided more cost effectively through private enterprise. In a memorandum sent to the heads of all Executive departments and agencies, the Reagan Administration confirmed its support of OMB Circular A-76. This shift to private enterprise is intended to enhance cost-efficient performance within the Federal government and utilize the private market whenever possible.

The streamlining process which is being encouraged by the Reagan Administration encompasses every area of government. The concept of cutting the size of government by shifting the activities to the private sector has a potentially wide application. In the area of laboratory accreditation, shifting responsibility for actual accreditation to the private sector is a rational move in the direction of reducing government involvement; and the private sector is prepared to undertake this burden.

Laboratory accreditation programs can and should operate in the private sector. In making this adjustment, most private sector programs can be expected to be financially self-sufficient. In so doing, this will tend to relieve the current burden on the Federal budget. Transfer of the actual accreditation of laboratories to the private sector should begin now, with the Federal government performing in a role as an accreditor of accreditation systems.

The precedent for the establishment of a program to accredit accreditation systems is supported by procedures already in operation in the United States' Department of Education for the accreditation of systems that accredit educational institutions. This program has been operated successfully for some years and specifies criteria such as scope of operations; responsibility, to include clearly identified needs, responsiveness to the public interest, and due process in accrediting procedures; a willingness to foster ethical practices among the institutions and programs which it accredits; and maintenance of program evaluation, reliability and autonomy. The regulation setting out the criteria for the establishment of a program to accredit educational accreditation systems is attached as an appendix to this paper. And, in the area of laboratory accreditation, beginning the transition process now will serve to phase out existing NVLAP programs as private sector accreditation systems expand and refine their accreditation capabilities.

Because there are a large number of laboratory accreditation programs, not all of the same competence and quality, the manufacturer, consumer or government need to have a basis to know if these systems are technically competent to accredit laboratories. Since these laboratories provide test data to support claims of conformity of products with voluntary standards, these accrediting systems provide a fundamentally essential service.

Of the seventy accreditation systems operating in the United States, only the AALA and NVLAP have for a number of years had accreditation of laboratories as their primary purpose. Except for AALA and NVLAP, all other accreditation systems cited in the DOC report relate to a limited area of testing or a product or groups of products. The data are then employed as the basis for material or product certification.

It is clear that the private sector is prepared to assume the burden of voluntary laboratory accreditation and assume the NVLAP functional mantle as NVLAP transitions into a new and more proper role as an accreditor of accreditation systems and as the primary United States link with the international laboratory accreditation community.

AALA, for example, patterned after Australia's National Association of Testing Authorities (NATA), organizes its accreditation system by discipline, and recognizes the same disciplines as NATA, except that AALA has added the discipline of Construction Material Testing and is considering the possible addition of a Geo-technical discipline.

Laboratories are accredited for the performance of specific tests or group of tests within a given discipline. Each laboratory may, of course, be accredited for more than one discipline and for more than one subdiscipline within each discipline. This approach permits laboratories to be evaluated for the entire range of their capabilities rather than requiring a separate process for each test and product. This approach will enable AALA to process a substantial number of quality accreditations in a reasonable period of time.

On the other hand, we recognize the serious problems which are inherent in establishing voluntary laboratory accreditation systems in the private sector. Our systems must show a balanced representation across government and the private spectrum. Information must be disseminated fairly, completely, and effectively. Advertising must be contained and controlled, and a solid, well-accepted technically accurate reaccreditation system must be established.

Fortunately, as I have noted before, the means to accomplish these serious tasks are at hand. There are, in being, independent, nonprofit organizations dedicated to voluntary laboratory accreditation which are able to maintain complete objectivity and balance in an accreditation system. Although AALA and NVLAP are the only general laboratory accreditation systems whose primary purpose is the accreditation of laboratories, many other systems exist for the basic purpose of certifying products and, in the process, accrediting laboratories which test those products.

Among these are:

- Windows and doors: Architectural Aluminum Manufacturers Association (AAMA)
- Glazing materials: Safety Glazing Certification Council (SGCC)
  Insulation Glass Certification Council (IGCC)
- Automotive parts: American Association for Motor Vehicle Administrators (AAMVA)

Once the concept of the government as an accreditor of accreditation systems is accepted, the criteria by which the government evaluates accreditation systems becomes of paramount importance. Fortunately, considerable work has been done already in establishing such criteria by the International Laboratory Accreditation Conference's (ILAC's) Task Force C during its recent meeting beginning on May 11 of this year and endorsed by its annual meeting held during the week of October 26 in Mexico City. This same concept is also being developed by consensus in American Society for Testing Material's Committee E-36 on Criteria for the Evaluation of Testing and Inspection Agencies. It seems sensible, therefore, to propose that the criteria developed by Task Force C be adopted, at least in draft form, subject to modification either by the ILAC committee or by the government acting in its capacity as an accreditor of accreditation systems.

The specific detail criteria have been discussed in the previous session, but I would like to highlight several paragraphs in the ILAC Task Force C Report. It is recommended, for example, that the laboratory accreditation system, such as AALA, must specify accreditation of testing laboratories in terms of nationally or internationally recognized standards and test methods in relation to well-defined fields of testing, scientific disciplines or technologies or in relation to specific products or tests. It further states that the criteria for accreditation must be published and generally available. A particularly important recommendation specifies that the evaluation of the technical competence of laboratories must be in terms of the International Organization for Standardization (ISO)/ILAC criteria which are consistent with ISO Guide 25. Finally, the guidelines require periodic reassessments of accredited laboratories and written reports by the assessors and a system which has an impartial or independent appeals procedures to resolve disputes associated with accreditation.

The ILAC criteria appear to require additional work and coordination, but the international implications of the work done so far are striking and would provide a solid basis for an ultimate interlocking network of global accreditation systems.

At this time we, in the private sector, are not certain how the voluntary laboratory system ultimately will evolve as a cooperative venture with government. We are convinced, however, that there will be a maturing and possibly a consolidating process where one or certainly a very few systems will emerge as the coordinating bodies for the private laboratory accreditation effort. Thus, we can offer you no ultimate model on the private side. We can only say with certainty that there is an undeniable need for a body in the United States whose major purposes are to accredit accreditation systems and to act as the international link for accreditation systems in the United States and those in other countries, presumably working within the ILAC structure. Therefore, we recommend strongly that to accomplish these critical missions the role of NVLAP be transformed to one of accrediting accreditation systems and provide that critical link with the international laboratory accreditation community.

A proposed logical sequence to accomplish this is as follows:

1. NVLAP discontinues establishing new laboratory accreditation programs

2. During a transition period, private sector accreditation systems will accept the NVLAP accredited laboratories until such time as the accreditation expires.

3. Documents concerning specific areas of the accreditation procedures, including applications, checklists, advertising policy, assessor qualifications, to name a few, must be reviewed and rewritten, if necessary.

4. And finally, we urge the adoption, at least in draft form, of the work done by Task Force C, Working Group 1 of ILAC, in creating criteria to be used in evaluating laboratory accreditation systems.

They may enroll under a U.S. Government-contracted group insurance policy.

(22 U.S.C. 2452(b)(6); 45 CFR 148.36)

CHAPTER IV—FOREIGN CURRICULUM CONSULTANTS

PART 10—TYPES OF ACTIVITIES

§ 10.1 *Duties of a consultant.*

(a) A Foreign Curriculum Consultant may provide an institution with a wide variety of services. These may include:

(1) review of textbooks and other educational materials;

(2) evaluation of library holdings and recommendations for new acquisitions;

(3) preparation of new instructional materials for use in the classroom;

(4) development of new units of study;

(5) conduct of demonstration classes and workshops for teachers;

(6) speaking at community functions; and

(7) teaching (normally not to exceed one regular classroom course per semester).

(b) The particular needs of each applicant determine the types of activities to be performed by the consultant. These needs should be stated explicitly and fully in the application.

(22 U.S.C. 2452(b)(6); 45 CFR 148.41, 148.42)

PART 11—APPLICATIONS—[RESERVED]

PART 12—REPORTS—[RESERVED]

[41 FR 10201, Mar. 9, 1976, as amended at 45 FR 22535, Apr. 3, 1980]

PART 149—COMMISSIONER'S RECOGNITION PROCEDURES FOR NATIONAL ACCREDITING BODIES AND STATE AGENCIES

Subpart A—Criteria for Nationally Recognized Accrediting Agencies and Associations

Sec.

149.1 Scope.
149.2 Definitions.
149.3 Publication of list.
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149.20 Scope.
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149.23 Initial recognition, and re-evaluation.
149.24 Criteria for State agencies.

Subpart A—Criteria for Nationally Recognized Accrediting Agencies and Associations

AUTHORITY: (20 U.S.C. 403(b), 1085(b), 1141(a), 1248(11)); (42 U.S.C. 293a(b), 295f-3(b), 295h-4(1)(D), 298b(f)); (8 U.S.C. 1101(a)(15)(F)); (12 U.S.C. 1749c(b)); (38 U.S.C. 1775(a)), unless otherwise noted.

SOURCE: 39 FR 30042, Aug. 20, 1974, unless otherwise noted.

§ 149.1 Scope.

Accreditation of institutions or programs of institutions by agencies or associations nationally recognized by the U.S. Commissioner of Education is a prerequisite to the eligibility for Federal financial assistance of institutions and of the students attending such institutions under a wide variety of federally supported programs. The recognition of such agencies is reflected in lists published by the Commissioner in the FEDERAL REGISTER. Inclusion on such list is dependent upon the Commissioner's finding that any such recognized agency or association is reliable authority as to the quality of training offered. The Commissioner's recognition is granted and the agency or association is included on the list only when it meets the criteria established by the Commissioner and set forth in § 149.6 of this part.

§ 149.2 Definitions.

"Accrediting" means the process whereby an agency or association grants public recognition to a school, institute, college, university, or specialized program of study which meets certain established qualifications and educational standards, as determined through initial and periodic evaluations. The essential purpose of the accreditation process is to provide a professional judgement as to the quality of the educational institution or program(s) offered, and to encourage continual improvement thereof;

"Adverse accrediting action" means denial of accreditation or preaccreditation status or the withdrawal of accreditation or preaccreditation status;

"Agency or association" means a corporation, association, or other legal entity or unit thereof which has the principal responsibility for carrying out the accrediting function;

"Institutional accreditation" applies to the total institution and signifies that the institution as a whole is achieving its educational objectives satisfactorily;

"Regional" means the conduct of institutional accreditation in three or more States;

"Representatives of the public" means representatives who are laymen in the sense that they are not educators in, or members of, the profession for which the students are being prepared, nor in any way are directly related to the institutions or programs being evaluated;

(20 U.S.C. 1141(a))

[39 FR 30042, Aug. 20, 1974, as amended at 45 FR 22536, Apr. 3, 1980]

§ 149.3 Publication of list.

Periodically the U.S. Commissioner of Education will publish a list in the FEDERAL REGISTER of the accrediting agencies and associations which he determines to be reliable authorities as to the quality of training offered by educational institutions or programs, either in a geographical area or in a specialized field. The general scope of the recognition granted to each of the listed accrediting bodies will also be listed.

(20 U.S.C. 1141(a))

§ 149.4 Inclusion on list.

Any accrediting agency or association which desires to be listed by the Commissioner as meeting the criteria set forth in § 149.6 should apply in writing to the Director, Accreditation and Institutional Eligibility Staff, Bureau of Postsecondary Education, Office of Education, Washington, D.C. 20202.

§ 149.5 Initial recognition, and renewal of recognition.

(a) For initial recognition and for renewal of recognition, the accrediting agency or association will furnish information establishing its compliance with the criteria set forth in § 149.6. This information may be supplemented by personal interviews or by review of the agency's facilities, records, personnel qualifications, and administrative management. Each agency listed will be reevaluated by the Commissioner at his discretion, but at least once every four years. No adverse decision will become final without affording opportunity for a hearing.

(b) In view of the criteria set forth in § 149.6, it is unlikely that more than one association or agency will qualify for recognition (1) in a defined geographical area of jurisdiction or (2) in a defined field of program specialization within secondary or postsecondary education. If two or more separate organizations in a defined field do seek recognition, they will both be expected to demonstrate need for their activities and show that they collaborate closely so that their accrediting activities do not unduly disrupt the affected institution or program.

(20 U.S.C. 1141(a))

§ 149.6 Criteria.

In requesting designation by the U.S. Commissioner of Education as a nationally recognized accrediting agency or association, an accrediting agency or association must show:

(a) *Functional aspects.* Its functional aspects will be demonstrated by:

(1) Its scope of operations:

(i) The agency or association is national or regional in its scope of operations.

(ii) The agency or association clearly defines in its charter, by-laws or accrediting standards the scope of its activities, including the geographical area and the types, and levels of institutions or programs covered.

(2) Its organization:

(i) The agency or association has the administrative personnel and procedures to carry out its operations in a timely and effective manner.

(ii) The agency or association defines its fiscal needs, manages its expenditures, and has adequate financial resources to carry out its operations, as shown by an externally audited financial statement.

(iii) The agency's or association's fees, if any, for the accreditation process do not exceed the reasonable cost of sustaining and improving the process.

(iv) The agency or association uses competent and knowledgeable persons, qualified by experience and training, and selects such persons in accordance with nondiscriminatory practices:

(A) To participate on visiting evaluation teams; (B) to engage in consultative services for the evaluation and accreditation process; and (C) to serve on policy and decision-making bodies.

(v) The agency or association includes on each visiting evaluation team at least one person who is not a member of its policy or decision-making body or its administrative staff.

(3) Its procedures: (i) The agency or association maintains clear definitions of each level of accreditation status and has clearly written procedures for granting, denying, reaffirming, revoking, and reinstating such accredited statuses.

(ii) The agency or association, if it has developed a preaccreditation status, provides for the application of criteria and procedures that are related in an appropriate manner to those employed for accreditation.

(iii) The agency or association requires, as an integral part of its accrediting process, institutional or program self-analysis and an on-site review by a visiting team.

(A) The self-analysis shall be a qualitative assessment of the strengths and limitations of the institution or program, including the achievement of institutional or program objectives, and should involve a representative portion of the institution's administrative staff, teaching faculty, students, governing body, and other appropriate constituencies.

(B) The agency or association provides written and consultative guidance to the institution or program and to the visiting team.

(b) *Responsibility.* Its responsibility will be demonstrated by the way in which—

(1) Its accreditation in the field in which it operates serves clearly identified needs, as follows:

(i) The agency's or association's accreditation program takes into account the rights, responsibilities, and interests of students, the general public, the academic, professional, or occupational fields involved, and institutions.

(ii) The agency's or association's purposes and objectives are clearly defined in its charter, by-laws, or accrediting standards.

(2) It is responsive to the public interest, in that:

(i) The agency or association includes representatives of the public in its policy and decision-making bodies, or in an advisory or consultative capacity that assures attention by the policy and decision-making bodies.

(ii) The agency or association publishes or otherwise makes publicly available:

(A) The standards by which institutions or programs are evaluated;

(B) The procedures utilized in arriving at decisions regarding the accreditation status of an institution or program;

(C) The current accreditation status of institutions or programs and the date of the next currently scheduled review or reconsideration of accreditation;

(D) The names and affiliations of members of its policy and decision-making bodies, and the name(s) of its principal administrative personnel;

(E) A description of the ownership, control and type of legal organization of the agency or association.

(iii) The agency or association provides advance notice of proposed or revised standards to all persons, institutions, and organizations significantly affected by its accrediting process, and provides such persons, institutions and organizations adequate opportunity to comment on such standards prior to their adoption.

(iv) The agency or association has written procedures for the review of complaints pertaining to institutional or program quality, as these relate to the agency's standards, and demonstrates that such procedures are adequate to provide timely treatment of such complaints in a manner that is fair and equitable to the complainant and to the institution or program.

(3) It assures due process in its accrediting procedures, as demonstrated in part by:

(i) Affording initial evaluation of the institutions or programs only when the chief executive officer of the institution applies for accreditation of the institution or any of its programs;

(ii) Providing for adequate discussion during an on-site visit between the visiting team and the faculty, administrative staff, students, and other appropriate persons;

(iii) Furnishing, as a result of an evaluation visit, a written report to the institution or program commenting on areas of strengths, areas needing improvement and, when appropriate, suggesting means of improvement and including specific areas, if any, where the institution or program may not be in compliance with the agency's standards;

(iv) Providing the chief executive officer of the institution or program with an opportunity to comment upon the written report and to file supplemental materials pertinent to the facts and conclusions in the written report of the visiting team before the accrediting agency or association takes action on the report;

(v) Evaluating, when appropriate, the report of the visiting team in the presence of a member of the team, preferably the chairman;

(vi) Providing for the withdrawal of accreditation only for cause, after review, or when the institution or program does not permit reevaluation, after due notice;

(vii) Providing the chief executive officer of the institution with a specific statement of reasons for any adverse accrediting action, and notice of the right to appeal such action;

(viii) Establishing and implementing published rules of procedure regarding appeals which will provide for:

(A) No change in the accreditation status of the institution or program pending disposition of an appeal;

(B) Right to a hearing before the appeal body;

(C) Supplying the chief executive officer of the institution with a written decision of the appeal body, including a statement of specifics.

(4) It has demonstrated capability and willingness to foster ethical practices among the institutions or programs which it accredits, including equitable student tuition refunds and nondiscriminatory practices in admissions and employment.

(5) It maintains a program of evaluation of its educational standards designed to assess their validity and reliability.

(6) It secures sufficient qualitative information regarding the institution or program which shows an on-going program evaluation of outputs consistent with the educational goals of the institution or program.

(7) It encourages experimental and innovative programs to the extent that these are conceived and implemented in a manner which ensures the quality and integrity of the institution or program.

(8) It accredits only those institutions or programs which meet its published standards, and demonstrates that its standards, policies, and procedures are fairly applied and that its evaluations are conducted and decisions rendered under conditions that assure an impartial and objective judgment.

(9) It reevaluates at reasonable intervals institutions or programs which it has accredited.

(10) It requires that any reference to its accreditation of accredited institutions and programs clearly specifies the areas and levels for which accreditation has been received.

(c) *Reliability.* Its reliability is demonstrated by—

(1) Acceptance throughout the United States of its policies, evaluation methods, and decisions by educators, educational institutions, licensing bodies, practitioners, and employers;

(2) Regular review of its standards, policies and procedures, in order that the evaluative process shall support constructive analysis, emphasize factors of critical importance, and reflect the educational and training needs of the student;

(3) Not less than two years' experience as an accrediting agency or association;

(4) Reflection in the composition of its policy and decisionmaking bodies of the community of interests directly affected by the scope of its accreditation.

(d) *Autonomous.* Its autonomy is demonstrated by evidence that—

(1) It performs no function that would be inconsistent with the formation of an independent judgment of the quality of an educational program or institution;

(2) It provides in its operating procedures against conflict of interest in the rendering of its judgments and decisions.

(20 U.S.C. 1141(a))

Subpart B—Criteria for State Agencies

Authority: Sec. 438(b) of the Higher Education Act of 1965, Pub. L. 89-329 as amended by Pub. L. 92-318, 86 Stat. 235, 264 (20 U.S.C. 1087-1(b)), unless otherwise noted.

Source: 39 FR 30042, Aug. 20, 1974, unless otherwise noted.

§ 149.20 Scope.

(a) Pursuant to section 438(b) of the Higher Education Act of 1965 as amended by Pub. L. 92-318, the United States Commissioner of Education is required to publish a list of State agencies which he determines to be reliable authorities as to the quality of public postsecondary vocational education in their respective States for the purpose of determining eligibility for Federal student assistance programs administered by the Office of Education.

(b) Approval by a State agency included on the list will provide an alternative means of satisfying statutory standards as to the quality of public postsecondary vocational education to be undertaken by students receiving assistance under such programs.

(20 U.S.C. 1087-1(b))

§ 149.21 Publication of list.

Periodically the U.S. Commissioner of Education will publish a list in the Federal Register of the State agencies which he determines to be reliable authorities as to the quality of public postsecondary vocational education in their respective States.

(20 U.S.C. 1087-1(b))

§ 149.22 Inclusion on list.

Any State agency which desires to be listed by the Commissioner as meeting the criteria set forth in § 149.24 should apply in writing to the Director, Accreditation and Institutional Eligibility Staff, Bureau of Postsecondary Education, Office of Education, Washington, D.C. 20202.

(20 U.S.C. 1087-1(b))

§ 149.23 Initial recognition, and re-evaluation.

For initial recognition and for renewal of recognition, the State agency will furnish information establishing its compliance with the criteria set forth in § 149.24. This information may be supplemented by personal interviews or by review of the agency's facilities, records, personnel qualifications, and administrative management. Each agency listed will be reevaluated by the Commissioner at his discretion, but at least once every four years. No adverse decision will become final without affording an opportunity for a hearing.

(20 U.S.C. 1087-1(b))

§ 149.24 Criteria for State agencies.

The following are the criteria which the Commissioner of Education will utilize in designating a State agency as a reliable authority to assess the quality of public postsecondary vocational education in its respective State.

(a) *Functional aspects.* The functional aspects of the State agency must be shown by:

(1) *Its scope of operations.* The agency:

(i) Is statewide in the scope of its operations and is legally authorized to approve public postsecondary vocational institutions or programs;

(ii) Clearly sets forth the scope of its objectives and activities, both as to kinds and levels of public postsecondary vocational institutions or programs covered, and the kinds of operations performed;

(iii) Delineates the process by which it differentiates among and approves programs of varying levels.

(2) *Its organization.* The State agency:

(i) Employs qualified personnel and uses sound procedures to carry out its operations in a timely and effective manner;

(ii) Receives adequate and timely financial support, as shown by its appropriations, to carry out its operations;

(iii) Selects competent and knowledgeable persons, qualified by experience and training, and selects such persons in accordance with nondiscriminatory practices, (A) to participate on visiting teams, (B) to engage in consultative services for the evaluation and approval process, and (C) to serve on decision-making bodies.

(3) *Its procedures.* The State agency:

(i) Maintains clear definitions of approval status and has developed written procedures for granting, reaffirming, revoking, denying, and reinstating approval status;

(ii) Requires, as an integral part of the approval and reapproval process, institutional or program self-analysis and onsite reviews by visiting teams, and provides written and consultative guidance to institutions or programs and visiting teams.

(A) Self-analysis shall be a qualitative assessment of the strengths and limitations of the instructional program, including the achievement of institutional or program objectives, and should involve a representative portion of the institution's administrative staff, teaching faculty, students, governing body, and other appropriate constituencies.

(B) The visiting team, which includes qualified examiners other than agency staff, reviews instructional content, methods and resources, administrative management, student services, and facilities. It prepares written reports and recommendations for use by the State agency.

(iii) Reevaluates at reasonable and regularly scheduled intervals institutions or programs which it has approved.

(b) *Responsibility and reliability.* The responsibility and reliability of the State agency will be demonstrated by:

(1) Its responsiveness to the public interest. The State agency:

(i) Has an advisory body which provides for representation from public employment services and employers, employees, postsecondary vocational educators, students, and the general public, including minority groups. Among its functions, this structure provides counsel to the State agency relating to the development of standards, operating procedures and policy, and interprets the educational needs and manpower projections of the State's public postsecondary vocational education system;

(ii) Demonstrates that the advisory body makes a real and meaningful contribution to the approval process;

(iii) Provides advance public notice of proposed or revised standards or regulations through its regular channels of communications, supplemented, if necessary, with direct communication to inform interested members of the affected community. In addition, it provides such persons the opportunity to comment on the standards or regulations prior to their adoption;

(iv) Secures sufficient qualitative information regarding the applicant institution or program to enable the institution or program to demonstrate that it has an ongoing program of evaluation of outputs consistent with its educational goals;

(v) Encourages experimental and innovative programs to the extent that these are conceived and implemented in a manner which ensures the quality and integrity of the institution or program;

(vi) Demonstrates that it approves only those institutions or programs which meet its published standards; that its standards, policies, and procedures are fairly applied; and that its evaluations are conducted and decisions are rendered under conditions that assure an impartial and objective judgment;

(vii) Regularly reviews its standards, policies and procedures in order that the evaluative process shall support constructive analysis, emphasize factors of critical importance, and reflect the educational and training needs of the student;

(viii) Performs no function that would be inconsistent with the formation of an independent judgment of the quality of an educational institution or program;

(ix) Has written procedures for the review of complaints pertaining to institutional or program quality as these relate to the agency's standards, and demonstrates that such procedures are adequate to provide timely treatment of such complaints in a manner fair and equitable to the complainant and to the institution or program;

(x) Annually makes available to the public (A) its policies for approval, (B) reports of its operations, and (C) list of institutions or programs which it has approved;

(xi) Requires each approved school or program to report on changes instituted to determine continued compliance with standards or regulations;

(xii) Confers regularly with counterpart agencies that have similar responsibilities in other and neighboring States about methods and techniques that may be used to meet those responsibilities.

(2) Its assurances that due process is accorded to institutions or programs seeking approval. The State agency:

(i) Provides for adequate discussion during the on-site visit between the visiting team and the faculty, administrative staff, students, and other appropriate persons;

(ii) Furnishes as a result of the evaluation visit, a written report to the institution or program commenting on areas of strength, areas needing improvement, and, when appropriate, suggesting means of improvement and including specific areas, if any, where the institution or program may not be in compliance with the agency's standards;

(iii) Provides the chief executive officer of the institution or program with opportunity to comment upon the written report and to file supplemental materials pertinent to the facts and conclusions in the written report of the visiting team before the agency takes action on the report;

(iv) Provides the chief executive officer of the institution with a specific statement of reasons for any adverse action, and notice of the right to appeal such action before an appeal body designated for that purpose;

(v) Publishes rules of procedure regarding appeals;

(vi) Continues the approval status of the institution or program pending disposition of an appeal;

(vii) Furnishes the chief executive officer of the institution or program with a written decision of the appeal body, including a statement of its reasons therefor.

(c) *Capacity to foster ethical practices.* The State agency must demonstrate its capability and willingness to foster ethical practices by showing that it:

(i) Promotes a well-defined set of ethical standards governing institutional or programmatic practices, including recruitment, advertising, transcripts, fair and equitable student tuition refunds, and student placement services;

(ii) Maintains appropriate review in relation to the ethical practices of each approved institution or program.

(20 U.S.C. 1087-1(b))

FINDING AIDS

A list of CFR titles, subtitles, chapters, subchapters and parts and an alphabetical list of agencies publishing in the CFR are included in the subject index volume to the Code of Federal Regulations which is published separately and revised semiannually (January 1 and July 1).

Table of CFR Titles and Chapters
Alphabetical List of Agencies Appearing in the CFR
List of CFR Sections Affected

Part 4

FORMAL STATEMENTS PRESENTED BY ATTENDEES AT THE WORKSHOP

National Institute of
BUILDING SCIENCES

1015 Fifteenth Street, N W
Suite 700
Washington, D.C. 20005
(202) 347-5710

November 9, 1981

Dr. John C. Williams
Acting Director
Office of Product Standards Policy
Room 4709
U.S. Department of Commerce
Washington, D.C. 20230

Dear Dr. Williams:

The increase in product liability claims during the last decade, due at least in part to an increase in regulatory activity, has underscored the need for a nationally recognized system for building materials and products certification.

In 1974, Congress authorized the establishment of the National Institute of Building Sciences (NIBS). The Institute was charged with, among other specific functions and responsibilities, assisting with evaluating and prequalifying existing and new building technologies to facilitate their acceptance at Federal, State and local levels and their introduction into the marketplace. The Institute was directed to improve several areas of building regulation, including development of test methods and other evaluative techniques relating to building systems, subsystems, components, products and materials with due regard for consumer problems.

The Institute's continuing involvement in building product standards and certification stems from that statutory mandate. The Institute's Board of Directors, appointed by the President of the United States with the advice and consent of the Senate, and the Institute's Consultative Council, have assigned a high priority to the development of a nationwide system of product evaluation and prequalification based on performance criteria and standards.

The Institute has conducted preliminary investigations and has developed plans for continuing work on this and related issues affecting the building community. One of these related issues is the accreditation of laboratories.

In response to the announcement of the November 16-17, 1981 Workshop on Laboratory Accreditation sponsored by the National Bureau of Standards, U.S. Department of Commerce, the enclosed "Statement on Laboratory Accreditation by the National Institute of Building Sciences" has been developed and is herewith submitted.

The Institute requests the inclusion of this letter and the enclosed statement in the proceedings of the workshop. Also, the Institute would appreciate the opportunity to present the statement during the workshop.

The Institute is addressing the total issue of product evaluation and thus needs to be kept informed of related action by the Federal government as well as other participants in the building community. Accordingly, the Institute requests that the Department of Commerce keep the Institute informed of its actions on this subject, insofar as they relate to the building community.

Sincerely yours,

Joseph H Newman
Joseph Newman
Chairman of the Board of Directors

Gene Brewer
Gene C. Brewer
President

cc: Dr. Ernest Ambler, Director, National Bureau of Standards
The Honorable Malcolm Baldridge, Secretary, Department of Commerce

National Institute of
BUILDING SCIENCES

1015 Fifteenth Street, N.W.
Suite 700
Washington, D.C. 20005
(202) 347-5710

October 22, 1981

A STATEMENT ON LABORATORY ACCREDITATION BY THE NATIONAL INSTITUTE OF BUILDING SCIENCES (NIBS)

The subject of laboratory accreditation and the November NBS Workshop is of interest and concern to NIBS insofar as it relates to building products, materials, subsystems and systems, particularly to the certification of such items. In fact, the subject of certification and related topics is one of the highest priority issues in the NIBS 1982 Program Plan.

The process of laboratory accreditation relates to the determination of the technical competency and proficiency of a laboratory. This should not be confused with product/material certification which may or may not be based upon data from accreditated laboratories. Laboratory accreditation must be evaluated in the context of its purpose -- to assist in maintaining an acceptable level of quality in laboratories, and thus provide reliable test results upon which to base such efforts as product and material research, development and certification.

In response to the issues mentioned in the workshop announcement, NIBS is in favor of laboratory accreditation. Therefore, NIBS suggests that there should be a nationally recognized nationwide approach to laboratory accreditation as opposed to a multiplicity of uncoordinated systems. This would tend to eliminate the need for duplicate applications for accreditation.

Although agreement on the form and management of such a nationwide approach to laboratory accreditation has not yet been reached, the Institute is vitally interested in the outcome of the workshop and will continue to serve as a forum where all sectors of the building community can address the issue.

CONTRIBUTION TO THE DISCUSSION

P. G. Forrest
Head, National Testing Laboratory
Accreditation Scheme (NATLAS)
National Physical Laboratory
Middlesex, TW 11 OLW
United Kingdom

Thank you, Stanley, for giving me this opportunity to speak about the UK National Testing Laboratory Accreditation Scheme. NATLAS is a Government scheme based at the National Physical Laboratory and operated under the auspices of the Department of Industry. It is thus Britain's counterpart to NVLAP. I have therefore listened to the disucssion with great interest. I have been hesitant to intervene because the matter you are debating is essentially your domestic concern though the outcome could affect the UK. In any event NATLAS has been formally in existence in the UK for only a few weeks and I would not presume to offer you advice on how to manage your laboratory accreditation affairs.

2. However, in developing NATLAS we fully disucssed the two options you are considering at this workshop and it may be of interest to you to know the option we have taken and why. The forum for discussion in Britain was the Steering Committee appointed to guide the development of the scheme. The membership of the Committee includes representatives of testing laboratories, of their customers, and of organizations that operate laboratory accreditation systems. The question was whether NATLAS should accredit the existing systems and leave each of them to continue to operate to its own rules and standards or whether NATLAS should aim to incorporate the existing systems into one centrally controlled scheme with a single set of regulations and one accreditation standard that laid down the criteria that all laboratories must meet to be accredited.

3. We chose the latter option; in other words NATLAS will accredit laboratories, it will not accredit accrediting systems. We made this choice for 3 inter-related reasons. First, we believed that accreditation granted directly by government would carry more weight and give the laboratories greater standing --or to put it another way, direct accreditation by NATLAS would be more readily recognized and accepted by the laboratories' customers.

4. The second reason was that if we could persuade the existing systems to stop operating independently and to participate directly in NATLAS it would help to reduce the duplication or multiple assessment of laboratories by different systems (we could not of course achieve this if we simply accredited the systems). Here I can already report some success. We do not have the proliferation of accrediting systems in the UK that you have in the USA. Not counting certification bodies which cover the assessment of testing facilities as part of their general assessment of the manufacturers of the products they certify, I have identified 8. Of these, five have already agreed to participate in NATLAS and I believe the other 3 will do so when they have sorted out certain administrative problems. The 5 (Ministry of Defence, the Central Electricity Generating Board, the British Standards Institution, Lloyd's Register of Shipping, and the British Ready Mixed Concrete Association) have agreed to recognize NATLAS accredited laboratories, to encourage the laboratories they have accredited to join NATLAS, to discontinue, where practical to assess laboratories independently, and to provide assessors (for a fee) to operate on behalf of NATLAS.

5. Our third reason for choosing to accredit laboratories rather than accrediting systems was that we believed that it would be easier to gain acceptance overseas of the laboratories' results if NATLAS had accredited them directly. Moreover, we believed it would be easier to negotiate mutual recognition between NATLAS and other national laboratory accreditation schemes if it were centrally controlled and operated on the basis of a single set of regulations and a single set of accreditation criteria.

POSITION STATEMENT

W. D. Edsall
Manager of Quality Assurance
Allegheny Ludlum Steel Corporation
River Road
Brackenridge, Pennsylvania 15014

I'm Wally Edsall. I'm Manager of Quality Assurance for the Allegheny Ludlum Steel Corporation. I also represent the Committee on General Metallurgy of the American Iron and Steel Insititute which is the senior technical committee for the steel industry in this nation.

The lady from West Virginia mentioned we had two groups here. We don't have two groups here, we have three and possibly more. We have NVLAP, the NBS group; we have AALA, the ACIL group; and, we have major manufacturers operating many captive laboratories.

The steel industry operates about 700 laboratories, employing about 7,000 people. John Grant mentioned the petroleum industry yesterday. It operates probably the same quantity of laboratories. We operate these laboratories under continuous audit and survey by our customers. We sell almost all of our products to specifications. We don't believe there is anybody in the world that can test as well as we can and we stand on that statement day after day after day.

I keep hearing here, as I've been hearing for years, of this demand for outside third party evalution, accreditation, certification--pick your word. I have as yet to hear anyone give me precise proof of this demand. Where is the absolute proof that we captive laboratories must have outside third party certification? Nobody has said it from this podium. Possibly, for the ACIL people such third party certification is an absolute necessity. I can see the reason for it--dealing in the testing marketplace as they do. However, nobody has convinced me, nor the American Iron and Steel Institute technical people of the need at this minute for such certification. Should a need for this third party certification be proven, we suggest that the ACIL membership make the decision best suited to them and their business environment. Speaking for General Metallurgy of the AISI, and, I would suspect, for most of the large captive laboratory organizations, we would never accept AALA as a meaningful third party. Should, and I reiterate, should the need for outside third party certification be proven, such certification must carry the stamp of the United States Government to be meaningful in the world marketplace.

The United States Government should not attempt to perform such certification itself. It simply does not have the sufficient qualified people to survey and audit the tens-of-thousands of various laboratories that exist in this country. The Government should define the criteria for laboratory evaluation and accreditation in a manner similar to the eighteen quality assurance criteria of 10CFR50. Then, and here I join with my friends from AALA, the Federal Government should establish a structure to certify organizations who will do evalution and accreditation, such organizations as AALA, possibly ASTM, ASME, and similar organizations. Laboratories evaluated and accredited under such programs should receive a certificate bearing the imprint of the United States Government. Finally, the assigned agency of the United States Government should audit the implementation of programs it has certified.

Summarizing; first, I say we don't have one or two or three groups here, we have many groups; second, I don't have the proof of need yet which I have to have before I can consider recommending to the AISI that they spend the hundreds of thousands of dollars such a program would cost; third, given such proof that accreditation/certification is necessary, it must carry the Government stamp or it is meaningless.

That's the position of the American Iron and Steel Industry. I would be glad to discuss it with anyone at any time. Thank you.

COMMENTS ON THE AALA PROPOSAL PERTAINING TO LABORATORY ACCREDITATION

D. R. Barton
Senior Vice President
Underwriters Laboratories
333 Pfingsten Road
Northbrook, Illinois 60062

Mr. Chairman, I would like to make a few comments about the AALA proposal that has been presented.

We are a strong advocate of the proposition that a laboratory needs to establish its acceptance in the marketplace based on its performance. We do not believe that laboratory accreditation as such should or can be the basis of acceptance. Nevertheless, we do not oppose laboratory accreditation in principle, provided the programs are based on valid specific criteria and procedures for providing reasonable assurance of compliance.

In general, we have considered, and continue to consider, NVLAP an effective response to an identified need for accreditation of laboratories in specific product areas. For that reason, UL has supported NVLAP and is an active participant in two product areas--thermal insulation and carpeting.

Wishing to see the effectiveness of NVLAP maintained, we have also continued to make the Department of Commerce aware of some of our concerns. We are concerned that laboratory accreditation will be and in fact is being considered by some as synonymous with product certification, when at best it should be considered as only one of several elements in a certification system.

We are also concerned that to accommodate broader interest and participation in the NVLAP program, the requirements for participation will be diluted. For example, efforts are already being made to encourage the Department of Commerce to accredit by discipline rather than by product. We do not feel that valid laboratory accreditation is possible without identifying the specific products and test methods to which it applies and tailoring the criteria accordingly. Our experience in safety testing indicates that without such limitation there is little likelihood of a high degree of uniformity in test procedures or test results. While expressing these concerns, we feel that NVLAP should continue to operate accreditation programs in specific areas where a real need is determined to exist.

Regarding the other major issue, we seriously question the proposal that NVLAP assume the role of an accreditor of laboratory accreditiation systems. There are many special purpose laboratory accreditation programs in the public and private sectors that have been designed, established, and operated by various accrediting authorities to serve their own needs. The fact that these programs have been operated successfully by Federal, State, and local goverment agencies, trade associations, professional societies, and other private organizations for a number of years without a higher level of supervision must raise serious question as to the need for a centralized function at the federal level as proposed.

In our view, the accreditation of laboratory accreditation systems is an unnecessary function that will only impose additional cost that must be passed on to the consumer. Such scheme for the accreditation of a broad spectrum of systems would of necessity be based only on generic and extremely broad criteria and would not add to the quality of accredited laboratories. Yet, the accreditation of an accreditation system by a federal agency would lend an aura of credibility to the quality and performance of the system (and the laboratories accredited under the system) that would not be justified under the degree of supervision which the Federal agency most likely could provide under the proposal.

The role of the Department of Education in accrediting systems for the accreditation of educational institutions has been cited by AALA as a model for the role to be assumed by the Department of Commerce. It should be noted that this function was mandated by law as a condition to the granting of federal funds for the support of educational institutions. To quality for federal funds, an educational institution had to be accredited by an accrediting body recognized and listed by the Department of Education. (This may sound uncomfortably familiar to the recent proposal that standards-writing organizations be listed by the Department of Commerce as a condition of recognition and participation by federal agencies.) We believe that in the case of privately operated businesses, such as those in the field of laboratory accreditation, such regulation is totally unnecessary.

In summary, UL is opposed to the transfer of the operation of NVLAP programs to AALA. UL has spent much time and money to obtain these formal accreditations and feels strongly that such programs should continue so long as there is a demonstrated need. UL prefers the NVLAP concept of laboratory accreditation as operated by NBS which is based upon integrity and absence of conflict of interest and reliance upon meaningful specific criteria related to the specific areas of accreditation.

UL is also opposed to assigning to the Department of Commerce the role of an accreditor of laboratory accreditation systems. We feel that this would constitute unnecessary regulation that would impose a burden of time and expense that would have to be absorbed by the consumer.

I appreciate the time you have given me to express my views on the proposal.

POSITION STATEMENT

R. A. Woodall
Senior Product Metallurgist
Latrobe Steel Company
Latrobe, Pennsylvania 15650

The Department of Commerce should not abandon its role, but it should be modified to provide expanded benefits at reduced cost. This might possibly be accomplished not by trying to deal with the almost unmanageable number of specific test criteria, either product or discipline oriented, but by dealing with the truly generic (or universal) concepts of good laboratory practice and offering qualification of the various laboratories' basic quality assurance systems. Such an effort must directly address the real economic problem of the proliferation of paperwork which is the subject of the final question posed by this workshop. This effort, combined with the traditional NBS role of developing and aiding in the supply of specific proficiency test samples should provide an adequate and viable charge for the DoC both domestically and internationally.

We also must observe that without economic restraints a little bit of need can quickly give birth to a bureaucratic nightmare. In view of the real international situation and the many expressed concerns for unbiased evaluation, I suggest that the DoC should neither substitute nor expand into the area of accrediting accreditors. Specific accreditation systems should, without a very substantial demonstration of other need, which I feel is now absent, be left to the well proven judgement of our free enterprise system.

AN OPINION ON LABORATORY ACCREDITATION POLICY

Geoscience Ltd
410 Cedros Avenue
Solana Beach, California 92075

It has been suggested that the accreditation of individual testing laboratories in the United States be performed by the American Association for Laboratory Accreditation based on the belief that it is better to accredit a laboratory by complete fields rather than by specific, standard tests.

There can be a danger in such a change from the normal accreditation procedure in that either (1) the quality of the performance of specific tests could be lowered (because of the broad scope involved), or (2) the services of smaller but high quality laboratories that offer only one or two test methods could be lost. In other words, it would be better to accredit by test method rather than by an entire field. NVLAP now performs this function.

There are additional important advantages in leaving the U.S. Government (the National Bureau of Standards/NVLAP) to act as the accrediting agency for testing laboratories be they independent, industrial, or academic. First of all, the National Bureau of Standards has an illustrious history of high level technical and scientific achievement that can be brought to bear on the accreditation procedure; outside, non-governmental organizations would have difficulty in equaling the capability and experience of the staff and facilities of the Government.

A second advantage in using NVLAP for laboratory accreditation is that the Government can be impartial and can more effectively balance the strong competitive forces that exist in industry relative to testing methods, procedures, and accuracy. All who have been involved in testing method debates in the technical community in the past years are familiar with the feuds and undue pressures that have prevailed; the Government has frequently moderated such disputes effectively. Only the Government (which has no predisposition for particular methods) can perform this function fairly.

Thirdly, the prestige of the U.S. Government (National Bureau of Standards/NVLAP) plays an important role in international acceptance of U.S. laboratory accreditation. Foreign countries would have greater confidence in laboratory accreditation if the U.S. Government performed that function.

Part 5

LETTERS RECEIVED COMMENTING ON PAPERS AND OTHER ASPECTS OF THE WORKSHOP PROCEEDINGS

GENSTAR
Building Materials

Genstar Stone Products Company
Executive Plaza IV
Hunt Valley, Maryland 21031
Telephone (301) 628-4000

Materials Testing Laboratory
Research • Technical Service • Quality Control

November 24, 1981

US DEPARTMENT OF COMMERCE
Room 3876
Washington, DC 20230

ATTN: Mr. John Locke
Coordinator, NVLAP

Dear John:

We wish to congratulate NBS, and yourself, on the recent two-day workshop as I feel it was well received throughout the materials industry. The gathering of interested parties, NVLAP, AELA, NRC, etc helped generate meaningful discussions. Certainly, if not meaningful, controversial, and I feel that it served to fortify the position of NVLAP and point out the increased need for certification in the industry. It is important that we centralize the certification into one specific area, and I feel it is appropriate for NBS to take the lead and develop an overall certification service, dealing in not only concrete and carpet, but steel, and any other areas that are required.

Although we have only been in the program for a little over a year, it has pointed out the need for certification in the concrete industry and helped us to prove our in-house monitoring of compression specimens and given us a tool to evaluate our laboratory vs others. It gives us leverage when we are involved in a testing dispute where other laboratories are not certified. It is important that the program continue and become more recognized so that we can eliminate the poor testing that occurs on many concrete placements. The poor testing techniques used by independent agencies, as well as the municipalities, causes untold problems and wasted time with meetings, paperwork, re-investigation of hardened concrete, etc. It is important that we either improve or eliminate the daily testing by those agencies and continue to push for certification of laboratories and technicians.

A point in passing is that NVLAP should expand the certification program in the concrete from the seven basic tests to evaluating methods of handling concrete mix designs and thereby improve the overall program. I would hesitate to add more paperwork, as that is quite heavy already; however, I again re-iterate that NVLAP should expand its involvement in the concrete area to more sophisticated methods of testing and evaluation.

It is important that we continue to emphasize the need for voluntary certification in order to improve the overall testing of concrete related and unrelated products. We need a centralized certification service, and NBS is the most appropriate agency to handle this effort.

Sincerely,

Robert L Chester
Robert L Chester, PE
Director
Research & Quality Control

RLCp

c: DJ Peters
R. Gaynor

LAW OFFICES
HOWARD I. FORMAN
PHILADELPHIA - WASHINGTON

CABLE ADDRESS
ALBIDALE
HUNTINGDON, VALLEY, PA.

PLEASE REPLY TO
(PHILADELPHIA OFFICE)
P. O. BOX 66
HUNTINGDON VALLEY, PA. 19006

November 27, 1981

Dr. Ernest Ambler, Director
National Bureau of Standards
Washington, D.C. 20234

Dear Dr. Ambler:

In your welcoming address at the opening of the "Workshop on Laboratory Accreditation: Future Directions in the United States",held at NBS on November 16-17, 1981, you indicated that there may be a need for future such workshops. Dr. Stanley Warshaw, who followed you, advised that persons wishing to do so could submit a formal statement regarding any of the topics or discussions at workshop to be included in the proceedings. This letter is intended to serve as such a statement, and I respectfully request that it be incorporated in the published record of the workshop.

Re: Laboratory Accreditation and International Trade

With regard to your comment that there may be a need for future such workshops, I wish to suggest that one should be held in the relatively near future at which at least a full day should be devoted to the general subject of International Laboratory Accreditation: Future Directions by the United States. A critical need exists to improve our international trade, as has been recognized in recent years by both the Carter and Reagan Administrations and the Congress in its enactment of the Trade Agreements Act of 1979. Along with that need there has been recognized as essential the removal of technical barriers to trade, and this has been stipulated in the GATT Code on Standards.

The U.S. has, since its inception in 1976, been a prime mover in the International Laboratory Accreditation Conferences (ILAC) which is designed to aid in the removal of technical barriers to trade by fostering the international reciprocal recognition of national programs for accreditation of testing laboratories. It is submitted that ILAC has advanced to a stage where serious consideration must be given by participating nations as to its future role in international trade. It is possible that an amendment to the GATT Code should be considered to incorporate in the Code some of the principles developed by ILAC. Another alternative may be to consider developing a treaty or agreement among the trading nations of the world to employ ILAC principles as part of their trading relationships and commitments, either on a voluntary or a mandatory basis. Even before the desirability of such new departures are decided upon there is a clear and present need to determine how and by whom U.S. policy and proposals in future ILAC conferences should be decided and presented at that international forum. All of these topics, and probably others, should merit the investment of time and resources to devote at least a full day to public discussion, hopefully based upon presentation of formal papers by representatives of the test laboratory community, industry, international trade, in the private sector, and the Departments of Commerce, State, Office of the Special Trade Representative in the public sector.

ALBIDALE-WINDMILL CIRCLE, HUNTINGDON VALLEY, PA. 19006 (215) 947-4154, 947-4769
SUITE 607-611 1000 CONNECTICUT AVENUE, WASHINGTON, D.C. 20006 (202) 659-2000

Re: Laboratory Accreditation in the United States

In the position I held as Deputy Assistant Secretary of Commerce for Product Standards Policy and Director of the Office of Product Standards Policy,from June 1, 1976 to May 31, 1981, I was the first person to be given the responsibility for the overall administration of the Commerce Department's National Voluntary Laboratory Accreditation Program (NVLAP). In that position I was exposed to many comments, pro and con, regarding the structure, operation, and usefulness of NVLAP, as well as proposals for changes to NVAP's modus operandi, all of which I heard repeated by the various speakers at the NBS workshop. In my position as a government official I tried to remain neutral in the face of competing claims and requests for changes to NVLAP, and to support only those actions which appeared to me to be, overall, in the public interest. In my present, private capacity I still prefer not to be drawn into any of the controversies over NVLAP, and will not be an advocate for any views except my own. In the hope that by setting forth some of those views I might help others who are directly involved and concerned with the accreditation of test laboratories in formulating or modifying their own positions, I will make the following observations.

1. Laboratory accreditation is useful to some laboratories and their clientele for one reason or another, is essential to some others, and possibly is a waste of resources to others. The "bottom line" in determining the value of accreditation by a third party should in most cases be an economic factor: i.e. will accreditation tend to bring more business to a laboratory? Laboratories might be well advised to have a market survey made to determine the answer to that economic question. If the potential benefits do not outstrip the costs, instead of investing in accreditation the laboratories might be better advised to invest in advertising or otherwise improving their public relations. On the other hand, if Federal, state or local governments, or manufacturers or other users of laboratories in the private sector require accreditation as a condition to using a laboratory or accepting its test data, or will tend to select laboratories on the basis of thir having been accredited by some third party, then accreditation will range from "useful" to "essential" depending upon the laboratory's economic position.

2. Governments (at any level) should not decide for private sector laboratories whether they should be accredited, or if the laboratories wish to become accredited who or what organization should do the accrediting. Such decisions should normally be made by the laboratories themselves. On the other hand, if governments have a "legitimate" need to have tests made by or for them by laboratories whose competency has been evaluated and adjudged satisfactory for a given purpose, governments should be able to require that the laboratories they will recognize have been so accredited by an "acceptable" accrediting agency...as long as they do not specify that the agency be an instrumentality of the government or so restrict the choice to a favored private sector accrediting body that there would be created a monopoly in such a body.

3. Governments should not operate laboratory accreditation programs unless to do so is considered (1) essential to carrying out an essential government operation, or (2) a consensus of the interested and concerned public convincingly demonstrates that there is a legitimate public need to be served and that it is desirable to have the government conduct such programs in preference to having it done otherwise.

4. NVLAP was instituted in response to a demonstrated need for the Federal government to provide such a service, the need having been presented to the Commerce Department by a consensus of a concerned segment of the public. As such, as long as NVLAP continues to serve the public interest, as determined by a consensus of the concerned public, it should be continued. If an updated consensus reveals that NVLAP is not serving the public interest properly or adequately it should be abolished, or if it can be modified to satisfy the clear, present-day desires of a consensus of the interested public it should be so modified. (Of course, in determining the consensus, the interests of other government entities should also be considered to determine whether elimination of or a change in NVLAP will seriously affect the carrying out of an essential government operation.)

5. In the five years of NVLAP's operation the independent test laboratory community, which was largely responsible for developing the consensus that led to the establishment of NVLAP, complained that NVLAP's modus operandi was such as to lead to the accreditation of too few laboratories to adequately solve the originally perceived need for such accreditation. The principal objection has been that NVLAP, by accrediting laboratories on a product by product or product by standard basis, rather than by the so-called generic "discipline" approach, was bogged down in operations with needless detail. One of the effects of this concern was the formation by the private sector of a "competing" organization called the American Association for Laboratories Accreditation (AALA) which is designed to accredit laboratories by discipline.

6. In recent years the independent laboratory community, principally the American Council of Independent Laboratories (ACIL), which fostered the development of AALA, informally proposed that the Commerce Department give up the product approach and have NVLAP shift to accreditation by discipline. In October 1978 Commerce published in the Federal Register a new, optional procedure (Part 7c in the Code of Federal Regulations) which provides that an organization such as AALA, ASTM, ASME, et al, if it operates by consensus and generally followed the due process criteria set forth in OMB Circular A-119 on Federal interaction with the voluntary standards system, could make its own finding of need, develop its own criteria for accreditation, and then apply to NVLAP to establish a laboratory accreditation program (LAP). This option makes it possible, in effect, for a private sector organization to develop a LAP employing the discipline approach, after which NVLAP would take over at that point and do the evaluation and accreditation of laboratories using that approach. Unfortunately, no private sector organization has to date availed itself of that option.

7. If the procedures of Part 7c do not meet the perceived needs of the private sector, and if they believe they could be better served by having a NVLAP option expressly state that it would provide for accreditation by discipline (along the lines adopted by AALA), ACIL or any other interested organization could direct a formal request to the Secretary of Commerce soliciting the establishment of a new option, which could become designated Part 7d, and if approved upon review by the interested public NVLAP would then be able to offer laboratories the choice of being accredited by product (Part 7a) or by discipline (Part 7c or Part 7d).

8. In view of the above options open to ACIL, et al, I submit that the oft-repeated objection to NVLAP on the basis of its accreditation by product is a "non-issue". The private sector could, if it met with approval in a public consensus, have NVLAP accredit laboratories by discipline following AALA's preferred procedures (or under Part 7c by somewhat different procedures). Possibly the opportunity offered the public of letting it choose from two (or three) types of NVLAP accreditation actions (with the Certificate of Accreditation specifically stating how the accreditation was arrived at) would have the advantage of satisfying those who favor one approach or the other.

9. The most recent proposal by ACIL and AALA was that NVLAP should gradually be changed to become an accreditor of organizations such as AALA that actually would do the accreditation of laboratories (instead of NVLAP). One of the reasons advanced for this proposed change (and also given previously when ACIL and AALA expressed the view that NVLAP should be eliminated entirely, and let private sector organizations such as AALA do the accreditation of laboratories) was that it would be consistent with a basic policy of the Reagan Administration, namely to remove from the Federal government's operations anything that could be done by the private sector.

10. I see nothing wrong with the basic premise that the Federal government should refrain from doing anything that the private sector is ready, willing and capable of doing (especially if it is already doing the same thing competently and adequately serving the public's needs), provided a consensus of the concerned and affected public agrees with any proposal which would change or even eliminate the Federal government's role. As I see it, the public's proper concern about such proposals is that they should be adopted if: (1) there is a material saving of funds to the taxpayer; and (2) the change will not materially diminish the effectiveness of the service provided by the government.

In deciding whether and how to change NVLAP it should be kept in mind that NVLAP, as it now operates, was designed to be self-sustaining by virtue of fees paid by applicants for accreditation after a limited number of years of Federal government expenditures as "seed money" to get the program under way. As for effectiveness, if only AALA should seek to be accredited by Commerce's NVLAP, as an approved accreditor of test laboratories, it may in time attain a status of credibility for its accreditation actions which will be the full equivalent of the accreditation actions of the Commerce/NBS "underwriters" of NVLAP activities. But it should be kept in mind that any change which will make NVLAP an accreditor of organizations such as AALA cannot be limited to just AALA. If other organizations now in being or created at a later date should seek to obtain an accreditation by NVLAP like that given AALA, they would have to be so accredited if they qualify. AALA itself, as well as Commerce, should consider what the effect that will have upon AALA and its competitors in serving the public's needs for the accreditation of laboratories.

11. In other words, it would appear that one possible motivation for ACIL's and AALA's desire to have NVLAP "disappear" or change its course of action is to eliminate NVLAP as an apparent competitor for whatever business there is in the accreditation of laboratories. (Obviously, as long as NVLAP continues in its present operations the opportunity for AALA to garner all or a major share of the laboratory accreditation business will be limited.) If AALA could become the single, thoroughly credible and widely accepted accreditor of laboratories, the public's interests could be well served. But if a number of private sector competitors of AALA should enter the scene, all equally accredited by NVLAP, it is questionable whether the public's (or AALA's) interests will be any better served than it is today with NVLAP and AALA as the "sole competitors" in the field.

12. It seems to me that ACIL-AALA have the burden of establishing, to the satisfaction of a consensus of the concerned and interested public, that the public interest will be better served by having NVLAP stop accrediting laboratories and instead accredit AALA (and possibly others) as a competent accreditor of laboratories, than by continuing the present state of affairs. As things now stand, test laboratories have, basically, three choices: (1) they can refrain from seeking accreditation by anyone; (2) they can, if they wish, seek accreditation by NVLAP: and (3) they can, if they wish, seek accreditation by AALA (and/or possibly other organizations). To establish that the change which ACIL-AALA are advocating will better serve the public interest it seems to me they will have to demonstrate that there will be a significant saving to the taxpayer, and that the effect of the change will be more beneficial to test laboratories and their clientele.

13. Lastly, I would like to point out that any change in the status or modus operandi of NVLAP may have some effect upon the U.S. involvement in the work carried on by ILAC. For this reason, before any decision is made by Commerce to change or refrain from changing NVLAP in any substantial way, I urge that the workshop on international laboratory accreditation be held in order to explore the possible effects of any such changes on our international trading relationships.

Sincerely,

Howard I. Forman

HIF/vjd

The Tanner Companies, United Metro Materials Division, P.O Box 20128, Phoenix, Arizona 85036, (602) 262-1211

November 30, 1981

NVLAP
Bldg. 225, Room B06
National Bureau of Standards
Washington, D.C. 20234

Re: Appreciation for NVLAP Certification Program

Dear Jim,

I would like to let you know how much we appreciate the opportunity to participate as a certified member of N.V.L.A.P.

As a supplier to the Ready Mix industry in Arizona, we feel very confident that our concrete is a quality product, because of the standards set forth in the NVLAP program.

The periodic inspection of equipment and the re-qualification of the technicians yearly, is an excellent standard. Also, the yearly inspection for re-certification by NBS.

The statistical evaluation of the concrete test results for the within-laboratory program have given us a realistic look at our ready mix program, because we not only obide by NVLAP standards, but we have adapted the program to be more effective for our own purpose.

We also like the between laboratory program, which involves us with another agency qualified under the NVLAP program to compare concrete cylinder results. This is excellent, because it tends to make us both try harder to do our testing as accurate as possible.

We appreciate the NVLAP program for many reasons. Most of all because it has helped us to organize our efforts to become more effective in our concrete testing and all our efforts are directed towards specific goals.

Sincerely yours,

Harold Wright

Harold Wright, Mgr.
Quality Control
United Metro Div.

HW/el

AMERICAN ASSOCIATION OF STATE HIGHWAY
AND TRANSPORTATION OFFICIALS

COMMITTEE CORRESPONDENCE

Address Reply to

November 30, 1981

Mr. James O. Bryson
Office of Testing Laboratory
Evaluation Technology
Building 225, Room B06
National Bureau of Standards
Washington, D.C. 20234

Dear Mr. Bryson:

The AASHTO Subcommittee on Materials which sponsors the AASHTO Materials Reference Laboratory (AMRL) under the Research Associate program of the National Bureau of Standards (NBS), offers the following comments for the record with respect to the November 16-17 Workshop on Laboratory Accreditation.

The AASHTO Subcommittee does not oppose the concept of the DoC taking on the role of an accreditor of organizations which, in turn, would accredit private sector testing laboratories provided this was not done in such a manner as to give a monopoly to any one organization. If the DoC was to change its role to such a position, the Subcommittee on Materials would want the option of modifying its AMRL operation such that it might become an accreditor of laboratories doing testing for highway materials.

On the other hand, the Subcommittee on Materials does not want to advocate any position that would result in an unnecessary proliferation of organizations that accredit testing laboratories. We believe that the present programs of the AMRL inspection of governmental and private laboratories, together with NVLAP program, are working reasonably well, though the Concrete LAP may be an unnecessary additional requirement as it may affect the State highway laboratories in the future. Consequently, we do not advocate a change such as was proposed by AALA. Rather, we would prefer that existing organizations such as AMRL and CCRL be used to their maximum effectiveness to limit the proliferation of accreditation programs.

Finally, to reinforce one statement made by the representative of the AISI at the workshop, the AASHTO Subcommittee on Materials would not be agreeable to the substitution of an AALA accreditation program for its AMRL program.

Your consideration of these comments in your evaluation of the workshop results will be appreciated.

Sincerely yours,

William Hurley

William D. Hurley, Chairman
AASHTO Subcommittee on Materials

cc: G.W. Steele, Chairman, AMRL Council
R.E. Hey, Secretary, AASHTO Subcommittee on Materials
F. Francois, Executive Director, AASHTO

SPARRELL ENGINEERING RESEARCH CORPORATION
POST OFFICE BOX 130, BRISTOL ROAD
DAMARISCOTTA, MAINE 04543
TEL 207-563-3224

December 1, 1981

U. S. Department of Commerce
National Bureau of Standards
Washington, DC 20234

Attention: Diana Kirkpatrick
Technology B06

Dear Dr. Kirkpatrick:

Subsequent to my attendance at the "Workshop on Laboratory Accreditation" held at the National Bureau of Standards, November 16-17, 1981, I would like to express my views on the meeting and the subjects discussed. In addition, I would like to comment on the present NVLAP Program and how it has effected my firm.

We are a small firm, probably one of the smallest firms currently under Accreditation by the NVLAP Program. We are accredited for but 3 test methods. Many of the speakers and attendees were representatives of much larger test laboratories, firms, or associations. I believe that it is important to express the views and concerns of a small test laboratory, which may or may not coincide with the views of larger organizations.

When we first considered enrollment in the NVLAP program in 1979, I must admit that I was very apprehensive about our joining the NVLAP Program. First, there was a question in my mind concerning the need for a program of this nature, whether it was one more intrusion of government into private industry, and finally, whether the investment in dollars and time, both of which are a precious commodity with a small firm, could be justified. Now, 2-1/2 years after our enrollment, I am pleased that we did join the program and I enthusiastically support its continuation.

One of the reasons that I initially decided to support the program, and still do, is that at the time of its initiation, I was aware of some very questionable tests results being produced by some test laboratories in the field of our interest, namely thermal measurements. This was particularly apparent with regard to test results on cellulosic insulations. I had seen advertised R values that, based on my 25 years of thermal test experience, were not realistic. On several specific occasions, I had clients that complained that their competitors were claiming R values that were half again higher than the test values that we were obtaining. It was obvious to me that there were laboratories generating test results more to the dictates of their clients than to the dictates of the laws of heat transfer. This was one of the reasons for our firm joining and supporting the NVLAP Program. It was indeed interesting to see the list of laboratories that enrolled. Almost without exception, these were the laboratories that were producing valid test results prior to the NVLAP Program. The labs that had produced questionable results did not enroll.

On the point involving government intrusion into private industry, I would like to say the following: Had the program been established under any other government agency but the National Bureau of Standards, I would have indeed been hesitant to enroll or support the program. NBS has always been considered by myself as the benchmark for integrity, accuracy, and often the final reference in my past laboratory work. Further, the fact that the program is conducted under the NBS auspices, carries beyond the work I conduct in my own laboratory, to the clients, for whom I perform this work and their appreciation of the validity of our work.

The third and last question that we had prior to enrollment, pertained to the investment, both in dollars and in time. In comparing our gross annual measurement business this year (1981) with the year in which we enrolled in NVLAP (1979), our measurement sales have almost tripled. Most of this increase is directly attributable to NVLAP enrollment and the result of our firm's name appearing on NVLAP Accreditation Lists. Prior to enrollment, most of our work came as second tier work from other laboratories not equipped for thermal testing. Now many clients come to us directly and in the process, make reference to our NVLAP Accreditation. If our increase in sales were solely attributable to our NVLAP enrollment, as most of it is, our investment in terms of enrollment and proficiency testing fees, is being returned to us at a rate of almost 20 fold per year.

In reference to the question of turning accreditation over to an independent association such as is proposed by "American Association for Laboratory Accreditation", I would like to make the following comments: I do not see how our laboratory, or the clients for whom we work, could hold any independent organization in as high an esteem as we do one under the direction of the National Bureau of Standards. I am afraid that it would lose much of its value and that we would be back where we were several years ago. Further, I am very concerned at the proposal to accredit by discipline as has been proposed. Where would that put our firm? We are accredited for but 3 specific tests. We are very well prepared, both in terms of equipment and personnel to perform these 3 tests. But 3 test procedures are not a discipline. We are not prepared, nor do I intend to expand our activities to satisfy, what I would consider the "Discipline of Thermal Measurements". I am afraid it would rule us out of such an accreditation program.

To conclude, I would like to repeat, although hesitant to join NVLAP at the beginning, I am now certainly glad that we did, and I would be very disappointed if it were not to continue with its fine work.

Very truly yours,
SPARRELL ENGINEERING RESEARCH CORPORATION

James K. Sparrell
President

JKS/eos

The American Society of Mechanical Engineers
United Engineering Center/345 E. 47th St., New York, N.Y. 10017/212-644-7722/TWX-710-581-5267

MELVIN R. GREEN, P.E.
Managing Director
Codes & Standards
212-644-7822

December 3, 1981

Mr. Stanley I. Warshaw
Director, Office of
  Engineering Standards
United States Department of Commerce
National Bureau of Standards
Washington, D.C. 20234

Subject: Laboratory Accreditation

Dear Dr. Warshaw:

In response to your letter of November 25, 1981 and commenting on the ACIL and AALA positions regarding this subject, The American Society of Mechanical Engineers (ASME) supports the concept that laboratory accreditation is a private sector activity. If there is a need for a body to accredit private sector organizations, that body should reside in the private sector.

Where a regulatory body references in its regulations a private sector accreditation activity, the regulatory body referencing the activity has an inherent overview role which provides criteria mutually acceptable to the regulatory body and the administrator for administering the accreditation activity. In the instances where a federal agency is the regulatory body referencing the private sector laboratory accreditation activity, the intrusion of NVLAP as the accreditor of private sector organizations would create a redundancy of regulatory bodies.

Sincerely,

M.R. Green

cc: W.E. Cooper

/sh

OWENS CORNING FIBERGLAS

OWENS-CORNING FIBERGLAS CORPORATION TECHNICAL CENTER: GRANVILLE, OHIO 43023

December 7, 1981

Mr. John W. Locke
NVLAP Coordinator
Room 3876
U. S. Department of Commerce
Washington DC 20230

Dear Mr. Locke,

This is in response to the call for comments in the Workshop on Laboratory Accreditation, November 16-17, 1981. This request was made by Stanley Warshaw when time was not available during the discussion period on Tuesday, November 17. Owens-Corning Fiberglas Corporation has been involved with NVLAP since its inception and these comments are based on our experience with the program.

There have been and still are many laboratory accreditation systems, but none have the national and international credibility and acceptance that the NVLAP program has gained in just a few years. This credibility and acceptance has been created because it is a voluntary program set up by Congress under the Department of Commerce; it has the support of the National Bureau of Standards; it has the product base system requested by the public sector; it uses existing consensus test methods; and it is responsive to public criticism.

In its few short years of existence, NVLAP has been accepted by local, state, and federal authorities. Dade County, Florida, considers NVLAP accreditation sufficient evidence that a laboratory is reputable. The California Energy Commission has discontinued its own accreditation system in favor of NVLAP laboratories. Other states such as Pennsylvania and Minnesota are considering using NVLAP laboratories rather than setting up their own accrediting systems. HUD, GSA, EPA, TVA and others are dropping their accrediting systems and will use NVLAP. The international accreditation systems such as ILAC have recognized the NVLAP system.

The broad acceptance of NVLAP is reducing the need for many special and duplicative accreditation systems. As more and more programs and laboratories come into NVLAP, it will become more self supporting. This reduction

in programs, and increase in self support appear to be a cost effective response to the need for laboratory accreditation. Therefore, there is no need for a program to accredit accreditors. This type of program would develop more accreditation systems which would destroy all the progress NVLAP has made for national and international laboratory accreditation.

Best regards,

Harland E. Fargo

H. E. Fargo, P.E.
R&D Services

HEF:jvs

DSET
LABORATORIES, INC.

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Black Canyon Stage
Phoenix, Arizona 85029

Telephone: 602-465-7356
Teletype: 910-950-4681 DSET PHX

December 3, 1981

Dr. Jack Williams
Office of Product Standards Policy
Room 3876
Department of Commerce
Washington, D.C. 20230

In re: NVLAP Program

Dear Dr. Williams:

As the nation's largest independent materials and solar testing facility, we are adamant in our position against the utilization of NVLAP as an accreditor of laboratories.

The interference of government in our business has been devastating as shown by the enclosed Testimony.

The AALA-ACIL proposal represents the best possible solution, and we support the AALA program as the future accreditor of our nation's laboratories.

Sincerely,

Joseph S. Robbins

Joseph S. Robbins
Chief Executive Officer

enclosure

Editor's Note: The statement referred to entitled "Government Competition with Small Business" was presented by Gene A. Zerlaut, President DSET Laboratories, Inc. before the Subcommittee on Advocacy and the Future of Small Business, Select Committee on Small Business, United States Senate on August 27, 1981, in Los Angeles.

Testing Engineers, Incorporated

Quality Assurance Services
Materials Consulting

December 8, 1981

Dr. Jack Williams
Office of Product Standards Policy
Dept. of Commerce, Room 3876
Washington, D.C. 20230

Subject: NVLAP

Dear Dr. Williams:

Please accept this as a testimonial in favor of changing NVLAP into a system of accrediting others' accrediation programs. More specifically, I am in complete agreement with the proposal to have the private sector organization "American Association for Laboratory Accreditation" (AALA) perform the day-to-day accreditation functions.

In addition, I would like to state in the strongest possible manner my feelings that any accreditation system must be discipline oriented, rather than the present approach.

I would add that our firm has participated in (and paid for) the National Bureau of Standards Cement & Concrete Reference Laboratory (CCRL) review for as long as I can remember (at least 12 years), so you must understand we are not anti-certification. But the NVLAP program, as it is currently structured, is just not workable or realistic.

Yours very truly,

M. Isaak

Merl Isaak
President

Pacific Inspection and Research Laboratory, Inc.
4076 148th Ave NE Redmond WA [illegible]

December 9, 1981

John W. Locke
NVLAP Coordinator
Department of Commerce
Room 4709
Washington D. C. 20230

RE: Laboratory Accreditation Programs

Dear Mr. Locke:

We received your report on the workshop on laboratory accreditations and would like to offer the following comments.

(1) I believe the Department of Commerce should cease its present role and turn to a private organization that would accredit the testing laboratories. The American Society for Testing and Materials is ideally suited for this purpose.

(2) The best action that can be taken to reduce the proliferation of inspections and paper work arising from duplicate accreditation activities within the United States would be to develop one nationally recognized program that would supersede all other efforts.

We are interested in obtaining more information on your NVLAP for concrete testing. Please send us the documents we need to apply for accreditation.

Thank you very much.

Sincerely,

Ronald O. Carlson
Ronald O. Carlson
President

ROC/bhm

HAUSER
LABORATORIES
5680 CENTRAL AVE P O BOX G, BOULDER, COLORADO 80306 • PH 303 443 4662

December 9, 1981

Mr. John W. Locke
NVLAP Coordinator
Department of Commerce
Room 4709
Washington, D.C. 20230

Re: Accreditation Programs

Dear Mr. Locke:

We appreciate your letter of November 30 inquiring the three main issues identified in the FR of August 12.

As a participant in the NVLAP thermal insulation program since its inception, we have no complaints other than limitation and cost. We can perform 2-3 times as many tests on insulation as we could justify for accreditation because of the cost. We once tested carpet, but the market in our geographical area did not justify applying for accreditation.

Our major income is from chemical analysis. The NVLAP concept of accreditation would be extremely cumbersome and expensive for this area of activity.

For these reasons, we prefer the AALA concept of accreditation by area of expertise.

We don't like anyone (even government) setting themselves up as a god. We see merit in having someone looking over the shoulder of anyone acting as an accreditation agency. Thus, I see merit in NVLAP reviewing accreditation procedures of AALA, and others who may presume such authority. I don't think that one lab should be accrediting others, as UL is proposing to do in certain areas.

We think it appropriate for the government to be involved in international laboratory accreditation, and see this as a valuable service of DOC.

Yours very truly,

HAUSER LABORATORIES

Ray L. Hauser

Ray L. Hauser, Ph.D.,
Research Director

RLH/ps

CAVANAUGH TOCCI ASSOCIATES, INC.
CONSULTANTS IN ACOUSTICS

WILLIAM J. CAVANAUGH, FASA
GREGORY C. TOCCI, PE, President

December 9, 1981

Mr. John W. Locke
NVLAP Coordinator
U.S. Department of Commerce
The Assistant Secretars for Productivity, Technology and Innovation
Washington, DC 20230

SUBJECT: Comments/Workshop on Laboratory Accreditation
Federal Register/46:202, Oct. 20, 1981

Dear Mr. Locke,

I respectfully submit the following comments on one of the three main issues identified in your memorandum of 30 November 1981 from the vantage point of a practicing professional consultant in acoustics. My comments pertain primarily to acoustical testing laboratories but may have general applicability.

Role of Dept of Commerce in Laboratory Acccreditation

I believe that DOC should retain its overall coordinating role in the laboratory accredatation program. However, under its general guidance and policy direction, the appropriate professional/technical/scientific societie(s) would undertake laboratory accreditation activities for all private sector laboratories providing testing services in their respective descipline. For example in acoustics, appropriate professional organizations might include the Acoustical Society of America (ASA), and the National Council of Acoustical Consultants (NCAC). A committee made up of representatives of each of these organizations might recieve and review requests by private sector laboratories for acceditation to perform specific acoustical tests (the laboratory requirements for accreditation would be previously established by the test method originating agency, ASTM, ANSI/ASA etc). An accreditation "panel of experts" would be named by the committee to handle the particular accreditation and, after review of all documentation submitted by the laboratory, visits to the laboratories as required, would recommend action with respect to accreditation. A standard and realistic fee for professional time and expenses would be established before hand for each test procedure.

It is my strong feeling that there is perhaps no single procedure that would be appropriate for all tests in all disciplines. Accordingly, the general procedure of professional organizations with cognizance of a particular technical area carrying out the accreditation procedure thru "panels of experts" with costs borne by the laboratory being accredited seems to be the only reasonable procedure. The Department of Commerce would of course retain an overall review and guidance role but it seems to me the real work of accreditation must be done by the professionals closest to the technical area involved.

Please advise if any clarification of the above comments are necessary or if I may be of further assistance in the development of this most important program.

Sincerely yours,

CAVANAUGH TOCCI ASSOCIATES, INC.

William J. Cavanaugh

cc: addressee
D. Lubman (NCAC)

KSU
KANSAS STATE UNIVERSITY

Comparative Toxicology Laboratories

Department of Surgery and Medicine
College of Veterinary Medicine
Veterinary Medical Center
Manhattan, Kansas 66506
913-532-5679

December 10, 1981

Dr. John W.Locke
NVLAP Coordinator
Department of Commerce
Room 4709
Washington, D.C. 20320

This is a response, Dr. Locke, to your November 30th mailing for comments on some of the issues identified in the August 12th Federal Register. I am specifically commenting on issues 1 and 3, since issue 2 (international laboratory accreditation activities...) is essentially a political and non-scientific issue.

In my opinion the Department of Commerce should limit its role in laboratory accreditation to recognizing those professional organizations which have the ability and the mechanisms available to accredit testing laboratories in their field of specialization. Essentially I am advocating that the various professions monitor themselves, and that the government reduce its activities to more of a serveillance and "quality assurance" status rather than an actual direct involvement in the accreditation procedure.

There are already several professional organizations established for accrediting laboratories, for example the Toxicology Laboratory Accreditation Board has the mechanism, qualifications, and motivation to adequately provide peer review and accreditation of laboratories performing toxicology testing and activities. This general philosophy is certainly in accord with the time-honored scientific system of peer review.

If such a peer-review system were instituted for a laboratory accreditation, the impact on duplication of inspections and paper work would be significant. Recognizing that "trust" is out of vogue in bureaucratic circles, I still morally must relate to the faith that we each have in our fellowman that he is doing the best he can and is essentially ethical. Certainly, the most heavily involved individuals that would suffer from unethical practices are the professions themselves, and they should be most highly motivated to provide the highest standards and best system of monitoring and inspection of their respective areas.

Thank you for this opportunity to comment. I wish you continuing success in your efforts to provide high quality standards for the professions.

Frederick W. Oehme, DVM, PhD
Director of Comparative Toxicology Laboratories
Professor of Toxicology, Physiology and Medicine

amd

CARPENTER TECHNOLOGY CORPORATION
CARPENTER STEEL DIVISION
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CarTech

December 11, 1981

Mr. John W. Locke
NVLAP Coordinator
Department of Commerce
Room 4709
Washington, DC 20230

COMMENTS ON LABORATORY ACCREDITATION

Responding to your letter of November 30, 1981, I would like to comment upon the issues which you listed from the Federal Register notice of August 12.

Commenting on whether the Department of Commerce should cease its present role and substitute in its place a program to accredit organizations which, in turn, would accredit private sector testing laboratories; I believe that this would be a sound program when more accreditor agencies are necessary to accredit those private sector laboratories voluntarily seeking accreditation. Our organization firmly believes that most laboratory accreditation should be on a voluntary basis. There are, possibly, some laboratories that may require federal accreditation due to the criticality of the processes or materials with which those laboratories are involved.

Regarding the maintenance of an effective United States presence in international laboratory accreditation activities, this subject would appear to be one which should be referred to ANSI. ANSI and the DOC should be able to come up with our best recommended action, again, in keeping with maintenance of accreditation on a voluntary basis. If the United States can base standards development on a voluntary system, then I would hope that we could convince other countries of the wisdom of the voluntary system. If foreign countries are unable to cope with a voluntary system, then I would hope that the United States would work hard at influencing each country to at least accept the system used within another country (voluntary or mandatory) as long as the content of a given country's system meets an international standard such as an ISO standard.

The private sector and government could reduce the proliferation of inspections and duplicative accreditation activities if reasonable voluntary standards could be developed for self accreditation. If regulations or other agreements would include requirements for meeting certain self accreditation standards, I am certain that many laboratories would proceed to do what needs to be done to meet such standards. Even without mandatory or legislated audits, enough large customers of every laboratory would certainly audit them out of enlighted self interest to put believability into the self-accreditation process just as is true for all other voluntary standards.

You can recognize that we are solidly behind the voluntary standardization process. We are convinced it works and that it does work because vendors and customers eventually establish such good relationships that confidence is maintained throughout the industrial community with respect to voluntary standards.

S. E. Tyson

S. E. Tyson
Manager
Quality Assurance

SET/dsg

COMMERCIAL TESTING CO., INC.

December 11, 1981

Mr. John W. Locke
NVLAP Coordinator
Department of Commerce, Room 4709
Washington DC 20230

Dear Sir:

In regard to your letter of November 30, I would like to make a few comments concerning the NVLAP workshop, as I was unable to attend due to a prior commitment.

ITEM 1 - I think the National Laboratory Accrediting Program would fail completely if private sector accrediting agencies were used. The present position of most regulatory authorities are that they do not know about NVLAP as administered by Federal agencies and have little faith in them. Using private sector agencies would add even less creditability if the National Buruea of Standard were not mentioned.

Secondly, the list of independent accreditors would probably grow to a vast number. Various regulatory agencies would list with the various accrediting agencies. Therefore, an independent testing laboratory would be required to be approved by essentially all of the accreditors. That would be extremely expensive.

ITEM 2 - A reciprocal agreement could be reduced so that a manufacturer selling in a foreign country would have test results accepted by regulatory authorities in that country if test results were provided by a NVLAP approved laboratory.

Continued......

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ITEM 3 - A test method should be approved and that approval carry over to other LAPS. For instance, we have dropped the ASTM E 84 tunnel test method in insulation in order to save money. Yet, the tunnel facility is approved for carpet. Why should we be required to pay a double fee for the same test method?

Finally, I believe that NVLAP is badly needed in this country. I feel that the NVLAP program should be pushed by the Department of Commerce into other Federal agencies who require laboratory certification and publicizing the program to the individual states and cities. For national building codes, such as CABO, BOCA, ICBO, or SBCCI, who require certification of laboratories, to urge them to accept NVLAP for its intended purpose, national certification by the ultimate authority, NBS. In my opinion, consensus standards organizations, such as ASTM and NFPA, who have "lists" of member laboratories, reference to NVLAP accreditation would publicize the program as well as add credence to the "list" of laboratories.

Thank you very much for allowing our comments concerning the NVLAP program. Please do not allow the NVLAP program to get discarded. It is the basis for a very much needed program.

Sincerely,

Jonathan Jackson

Jonathan Jackson
Executive Vice President

JJ:sy

GEORGE A. HOFFMANN, President
JOSEPH D. MURPHY, Vice President
J. P. VERHALEN, Treasurer

SHELDON H. CADY, Executive Vice President
KENNETH D. MENTZER, Director, Materials & Standards

mima
Mineral Insulation Manufacturers Association

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Summit N.J. 07901
(201) 277-1550

December 14, 1981

Mr. John W. Locke
NVLAP Coordinator
Room 3876
U. S. Department of Commerce
Washington, D. C. 20230

Dear Mr. Locke:

Since MIMA was one of the organizations instrumental in the inception of NVLAP, we think it necessary and appropriate to respond herein to the call for comments in the Workshop on Laboratory Accreditation on November 16-17, 1981.

None of the existing laboratory accreditation systems have the national and international credibility and acceptance that the NVLAP program has achieved in its brief existence. NVLAP's credibility and acceptance are the result of the following factors:

1). It is a voluntary program set up by Congress under the Department of Commerce.

2). It is supported by the National Bureau of Standards.

3). It has the product base system requested by the public sector.

4). It uses existing consensus test methods.

5). It is responsive to public criticism.

6). It has been accepted by certain local, state, and federal authorities. States have, or are considering using NVLAP laboratories rather than setting up their own accrediting systems. Government agencies, including HUD, GSA, EPA and TVA are also dropping their own accrediting systems and will use NVLAP.

7). International accreditation systems such as ILAC have recognized the NVLAP system.

It is our understanding that an alternative proposal considers turning laboratory accreditation over to the private sector. This would have a negative impact for several reasons and MIMA registers its strong opposition to this proposal.

This action would remove the "seal of the Federal Government" from the accreditation system thus losing the credibility and capability for those laboratories currently accredited and for those wishing to become accredited in the future. Streamlining of the accreditation process could provide for a less stringent program in the laboratory and further weaken the credibility of the entire program. Private sector operations would not necessarily be responsive to public criticism as is now the case under NVLAP.

It is our further concern that accreditation fees would be substantially raised if the private sector operation were adopted.

The broad acceptance of NVLAP is reducing the need for many special and duplicative accreditation systems. As more and more programs and laboratories participate in NVLAP, it will become more self-supporting and cost-effective.

We believe there is no need for a program to accredit accreditors. This type of program would develop more accreditation systems which would destroy all of NVLAP's progress to date for national and international laboratory accreditation.

Sincerely,

Sheldon H. Cady

Sheldon H. Cady
Executive Vice President

SHC/tkl

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December 14, 1981

John W. Locke
N.V.L.A.P. Coordinator
Department of Commerce
Room 4709
Washington, D.C. 20230

Dear Mr. Locke:

I am writing in response to one of the issues discussed at the recent workshop.

> "Whether the Department of Commerce should cease it's present role, and substitute in its place a program to accredit organizations which, in turn, would accredit private sector testing laboratories".

Before commenting on this issue, I feel some background is necessary. I am the Laboratory Manager for R. W. Sidley Quality Control Laboratory. R. W. Sidley, Inc., is a ready mix concrete, precast and construction supply producer. For several years before the establishment of the N.V.L.A.P. we sought accreditation for our Quality Control Operations. The fact that R. W. Sidley is a ready mix producer disqualified us from seeking accreditation. It was not until after the establishment of the N.V.L.A.P. that we could even be considered for accreditation.

Now that the Department of Commerce has spent their time and resources in developing a program to accredit private sector testing laboratories, these same accreditation organizations that turned down our application for accreditation for years, suddenly are sympathetic to the needs of private sector testing laboratories. I do not doubt that these organizations have done much good in improving the quality of concrete testing over the years, but, I can only hope that the Department of Commerce, the pioneers of the N.V.L.A.P., will remain in charge of the program they have worked so hard in establishing. It is indeed an honor to be in direct association with such organizations as the Department of Commerce, the National Bureau of Standards, and the N.V.L.A.P. Staff.

Sincerely,

R. W. SIDLEY, Inc.

Lawrence McCune

Lawrence McCune
Laboratory Manager

LM:mlo

Corporate Offices
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BRACKENRIDGE, PENNSYLVANIA 15014

December 14, 1981

Mr. John W. Locke
Coordinator, NVLAP
United States Department of Commerce
The Assistant Secretary for Productivity,
Technology and Innovation
Washington, DC 20230

Dear Mr. Locke,

The following comments pertain to the issues raised in your letter of November 30, 1981, relating to laboratory accreditation.

1) As NVLAP is the only existing national accreditation facility, I believe it should be continued in order to be available to those facilities which do require it until a longer term program is put into operation. Hopefully, during this period the voluntary consensus groups can create a meaningful criteria for laboratory accreditation.

2) Regarding international laboratory accreditation, the Department of Commerce should continue its participation in ILAC. An advisory group representing major industry associations should meet with the ILAC representatives to make certain that these representatives accurately reflect the major industrial interests of the United States.

3) The proliferation of quality assurance surveys and audits is a serious problem that needs to be resolved in the United States. The financial impact of these is truly significant on our industries. Dozens, possibly hundreds, of organizations have their

own programs which they mandate industry must meet. Almost inevitably one organization will not accept a program approved by another organization. If the consensus groups could create the previously mentioned accreditation criteria and the criteria for an evaluation program, we might be a large step closer to a single program which would be universally accepted. I'm thinking along the lines of an entirely voluntary program similar to the Canadian National Standards System's, Criteria and Procedures for Accreditation of Testing Organizations. In this country I believe such evaluation programs should be operated with peer group assessment with the option of central agency approval of the evaluation program and auditing of implementation.

Sincerely,

Mr. W.D. Edsall

W. D. Edsall
Manager, Quality Assurance

WDE:js
cc: Ms. Geraldine V. Cox, Chemical Manufacturers Association
Mr. John B. Guernsey, Jessop Steel Corporation
Mr. Howard C. Lacy, American Iron & Steel Institute
Mr. Robert A. Walsh, Allegheny Ludlum Steel Corporation

CRI
The Carpet and Rug Institute, Suite 700, 1629 K Street, N.W.,
Washington, D.C. 20006, 202/223-2578

December 15, 1981

Dr. Jack Williams
Office of Product Standards Policy
Room 3876
Department of Commerce
Washington, DC 20230

Re: Laboratory Accreditation by NBS

Dear Dr. Williams:

Three basic questions were posed during the NBS Workshop on Laboratory Accreditation on November 16 and 17, 1981:

1. Is there a need for laboratory accreditation?
2. Should DoC be accrediting laboratories directly or accrediting private sector agencies which will then accredit laboratories?
3. Should laboratories be accredited by product type or by technical discipline?

The answer to the first question obviously is, "Yes". The existence of (1) the 70 accrediting agencies listed in the DoC-Hyer report, (2) ASTM Committee E36 on Criteria for the Evaluation of Testing and Inspection Agencies, and (3) ASTM E548 Standard Practice for Generic Criteria for Use in the Evaluation of Testing and Inspection Agencies - not to mention in detail the international activities reported on at the workshop - all confirm that there is a real need for laboratory accreditation.

It may be questioned, however, whether there is a need for a national accreditation system since most of the 70 accreditation programs are limited in scope. In answering this question, and the other two questions generated by the workshop, we should consider what might be the objectives of a national laboratory accreditation system. The following three general objectives are suggested:

1. To bring the quality of test results from accredited laboratories up to a minimum acceptable level.
2. To obtain acceptance of accredited laboratory test results by municipal, county, state, regional, federal and international organizations and governmental agencies.
3. To reduce the cost of laboratory accreditation to the ultimate consumer.

The first two objectives will be achieved only if criteria of adequate rigor are applied consistently to all accredited laboratories seeking general recognition. In addition, to achieve the second objective the accrediting agency, itself, must possess the highest possible credentials in order to convince the people who rely on test results from accredited laboratories that they can indeed trust the data supplied. NBS has these credentials nationally and internationally.

The third objective, reducing the cost of accreditation, can be achieved (1) by a continuing program of refining the accreditation process so that it becomes more cost effective, and (2) by eliminating duplicate accreditation. Both of these functions can be carried out best by one accrediting system or agency.

The subject of duplicate accreditation involves the third question raised during the workshop - should laboratories be accredited by product or by discipline? The answer rests on the recognition that the item for which a laboratory is accredited is not the testing of a product or the testing within one discipline but rather the capability of testing one or more products according to a particular test method. Duplicate accreditation occurs (1) when one accrediting agency conducts two accreditation processes for the same test method on two different products, or (2) when two accrediting agencies conduct separate accreditation processes on the same test method for one or more products.

In accreditation by product a laboratory has the opportunity of being accredited for a group of test methods frequently used in the testing of one product. Often a laboratory will choose to obtain accreditation for only some of the test methods in the group - not for all of them. Similarly, in accreditation by discipline a laboratory has the opportunity of being accredited for a group of test methods frequently used in a general area of testing - electrical, chemical, acoustical, etc. Again, a laboratory often will choose to be accredited for only some of the test methods in the group - not for all of them.

The accreditation of a group of test methods, whether by product or by discipline, carries with it a minimum overhead cost that must be paid if accreditation is sought for only one of the test methods in the group or for all of them. The testing of many products involves test methods from several disciplines. Thus, with accreditation by discipline, in order to provide adequate service on a particular product a laboratory must obtain accreditation on a selection of test methods under a number of different disciplines, each having its own overhead charge. For many laboratories the discipline approach would appear to be inherently more expensive.

On the other hand, for the laboratory testing a wide range of products under a limited number of disciplines, accreditation by product could be more expensive. However, most accreditation programs were started to serve a product certification program and a large number of laboratories are equipped to carry out a battery of tests on a limited number of products. Nevertheless, without a detailed study of testing laboratories, we cannot choose between the two approaches to accreditation and assume that there is a need for both approaches - by product and by discipline.

The ways of reducing the cost of accrediting laboratories for a given test method, then, include the following:

1. Decrease the number of accrediting agencies for that test method so as to minimize overlap.
2. Provide for reciprocity between accrediting agencies.
3. Encourage agencies accrediting by product:
    a. To issue a general accreditation for all products to a laboratory for a particular test method once accreditation has been issued under two product accreditation programs.
    b. To reduce overhead charges to a laboratory being accredited under two or more product programs.
4. Encourage agencies accrediting by discipline to decrease overhead charges for multi-discipline accreditation of one laboratory.

Returning to the three questions raised during the workshop, our answers are:

1. There is a need for a national accreditation system to provide consistency in rigor and the greatest authority for acceptance by subnational, national and international organizations.

2. NBS should continue to accredit testing laboratories by product and should not be merely an accreditor of accrediting agencies. A formal accrediting of accrediting agencies will lead to an increase in the number of accrediting agencies instead of the decrease which is needed to reduce the cost of duplicate accreditation.

However, there is a need for establishing a basis for reciprocity between accrediting agencies. The preferred approach would be for other accrediting agencies to accept accreditation by NBS for those test methods accredited by NBS under one of the LAPs. Also, some agencies which now accredit by product may wish to have NBS assume responsibility for their programs in order to benefit from the national and international acceptance of an NBS NVLAP. Other federal agencies should be encouraged

to establish their accreditation programs using NBS rather than initiating independent programs.

The tax-dollar portion of the cost of the NVLAP can be reduced as more individual product LAPs are established and provide a broader base over which to distribute the program initiation costs of new LAPs. Furthermore, as the number of LAPs increases, the stature of the NBS program will also increase.

3. While we recognize there may be some latoratories for which accreditation by discipline is less costly, for the laboratories serving the carpet industry accreditation by product is more economical.

As you may have already noticed, in the preceding discussion we have designated NBS as the accrediting agency responsible for NVLAP, not DoC. In order to achieve the second objective of gaining worldwide acceptance, the national accreditation system must be known as the NBS system since it is NBS that has the technical prestige, not DoC.

As a final comment: we recommend NBS form an advisory committee composed of representatives from laboratories accredited under NVLAPs - one person for each LAP. Such a committee could make valuable suggestions for improving the effectiveness of the programs and for reducing their cost.

Sincerely yours,

Charles H Masland 3rd

Charles H. Masland 3rd, PhD
Chairman, CRI Laboratory
Subcommittee

CHM3rd/p

cc: Dr. Stanley I. Warshaw, Director
Office of Engineering Standards
National Bureau of Standards
Department of Commerce
Washington, DC 20234

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TENNECO

DWR1818Q1
December 15, 1981

Mr. John W. Locke
NVLAP Coordinator
Department of Commerce
Room 4709
Washington, D. C.   20230

Dear Sir:

This is in response to your letter of November 30, 1981 requesting comments on the accreditation of private sector testing laboratories. The following comments are keyed to the three points of your letter:

1. We believe that the accreditation of private sector testing laboratories should be left entirely within the private sector. It is felt that no additional consumer protection is gained by the establishment of government oversight, either by direct government accreditation or by government accreditation of private sector accreditation groups. Additionally, it is felt that government involvement tends to lend a measure of "official government approval" to testing laboratories and that as a result the consumer could be misled as to what accreditation means.

2. If international laboratory accreditation activity is within the private sector in another country, then our activity should remain within the private sector. It would seem that any privately held laboratory, or accreditation group, would seek involvement in international accreditation activity when such involvement would be economically attractive. It is felt that the involvement of the government in this activity is undesirable unless the activity is government-to-government.

3. This point seems to imply that "duplicative accreditation activity" is necessarily bad. Such activity could be considered competitive and therefore a positive contribution to accreditation activity. A privately held laboratory can select an accreditation group based on need, services performed, cost, and related factors. We see no need for action on this point except the withdrawal of any requirements imposed by government accreditation involvement.

Also, we believe that the private sector can respond much more quickly than the public sector to the needs of commerce and industry. We urge that the private sector be allowed to control accreditation activity

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since the establishment of a level of government involvement could result in highr costs to the laboratories being accredited.

Sincerely,

R. T. Clark, Jr.
Manager of Quality Assurance

DWRainey:ddp

cc:

A. J. Moberg (as discussed 12-11-81)

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December 15, 1981

John W. Locke
NVLAP Coordinator
Dept. of Commerce, Room 4709
Washington, D.C. 20230

Subject: Private Sector Testing Laboratory Accreditation

In answer to issue No. 1 in your letter dated 11-30-81: I personally feel the A.I.A. (American Insurance Association) should give private lab accreditation, due to the fact the A.I.A. has to follow through on their customer installations to be sure that they are installed properly, whether thay be space heaters, add-on furnaces, boilers or inserts (all solid fuel appliances). The only way an insurance agent would know whether the unit is installed properly is by the data plate, informing the agent of minumum clearance, the test standard in which the appliance was tested and labeled for each applicable application. And last, but not least, the agent will have an accurate and up to date list of private labs with accreditation.

In answer to issue No. 2, this will be answered in issue No. 3.

Issue No. 3: As a manufacturer in the ever growing solid fuel industry, I am totally frustrated!! In my attempt to test, label and sell a safe product for the consumer I thought a safe product was the goal for the consumer. At this point in time, my company's product has been tested and labeled as a safe product with proper clearance for installation.

My first problem is the third party testing agency. Not everyone in our fine country knows them due to the fact that no one is giving formal National Accreditation. There are only about twenty small private labs testing solid fuel products, some are good, some are not. This is causing no end to the confusion with local building officials.

U.L. is a standard writing organization, also testing to "the" standards. With their cost, lead time, and obvious monopoly in these types of services, I

felt it only just to have free enterprise work at its fullest, and have our products tested and labeled to the applicable standard by a proven lab.

My second problem is the standards themselves. Not every state accepts the U.L. standards. For example, the state of Maine has their own standard called ETLM standard 78-1. I can have my products tested by my third party testing agency for a sum of money. As their letter on procedure for product approval explains, they would be more than happy to test our product, however, their lab is half way across the country. Why is our product safe in Wisconsin and not in Maine? NO UNIFICATION! This results in duplication of costs and all is passed on to the consumer.

Another example is the state of Massachusetts. They only accept products tested to C.S.A. B-366-1979 standard. One very good reason Massachusetts does look at the C.S.A. standard is because the United States does not have a standard for solid fuel residential boilers. The U.S. only has A.S.M.E. covering the pressure vessel, this has nothing to do with clearance firings, pot or exterior temperatures. B-366-1979 does cover furnaces and boilers.

I must submit to all the following code officials with anywhere from $1000.00 to $ 2000.00 per model only to prove my lab product and test standards "possibly" meet their own requirements. This does take time and money. Again, no unification with much expense to the consumer. DUPLICATION. (BOCA-ICBO-HUD-TVA-SBCCI)

I maintain we hardly can entertain international laboratory accreditation activities when we don't even have our own back yard cleaned up!! The only way we can avoid duplication is by "one" organization having final authority on a national accepted standard. A.S.M.E. is a good example of this system working. I feel A.S.T.M. should have the final say (American Standard Test Methods), then the American Insurance Association giving testing laboratory accreditation.

Thank you for your time and consideration on my concerns.

Sincerely,

Donald E. Venzke

Donald E. Venzke
V. Pres-Production

cc: David Suchla

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December 16, 1981

Mr. Jim Bryson
NVLAP
National Bureau of Standards
Technology Building, Room B06
Washington, D. C. 20234

Dear Mr. Bryson:

I am writing, as requested by Bob Gladhill, on my feelings on the NVLAP program. I must say that I am a firm believer in the NVLAP program because it makes one keep his testing within the ASTM guidelines. It provides a means of regulation on testing labs which the State of Texas does not. I also feel that NVLAP should remain under the control of the National Bureau of Standards and the Department of Commerce. The reason I feel this way is because it adds an extra air of accredibility when I mention to a customer that the federal government helps assure that what I report is accurate information. The independent labs have a tendency to back up and start stuttering when confronted about being accredited.

I am proud to say that I am a part of NVLAP and thank you for the opportunity to say so.

Sincerely yours,

Chris G Slate

Chris G. Slate
Quality Control Manager

CGS:ww

american concrete institute

December 16, 1981

Mr. James O. Bryson
Member, ACI
Office of Test Lab Evaluation
Technology
National Bureau of Standards
Room B-04, Building 226
Washington D.C. 20234

Reference: National Voluntary Laboratory Accreditation Program (NVLAP)

Dear Jim:

We have elected to comment on the need for maintaining the NVLAP program for accrediting testing laboratories that test freshly mixed field concrete.

The progress of this program has been reviewed with ACI's representative who served on the "National Voluntary Accreditation Committee on Freshly Mixed Field Concrete", Mr. Howard Newlon, Jr., and it is our opinion that NVLAP is accomplishing its objectives. We understand that 55 laboratories have received a concrete LAP accreditation (after the beginning of 1982, 9 more will be accredited), and the program is well on its way to self-sufficiency.

There exists at the present time a cooperative interface between the NVLAP Program and the new ACI Certification Program that is being developed. These two programs will complement each other in sharing of resource material including workbooks, training films, testing procedures, etc. for certification of Concrete Technicians. This mutual alliance will be very important to both programs and should be continued.

Further it is our opinion, as expressed in the ACI letter of July 25, 1978 to the Department of Commerce regarding the need for this program, that the NVLAP activity fulfills a need within the concrete industry which probably cannot be handled by existing institutions in the private sector.

We hope that these comments about NVLAP are helpful. For background, the American Concrete Institute is a non-profit technical organization whose purpose is to further engineering and technical education and scientific research on concrete. Its efforts are accomplished by the voluntary work of ACI's 16,000 individual members who, through committees, seminars, research projects and/or publications, participate in the activities of ACI. ACI's membership is made up of engineers, architects, contractors, building officials, government representatives, concrete technicians and suppliers -- all of whom share a common interest in the use of concrete as a construction material.

Our ACI membership is interested in having good testing laboratory facilities for concrete and feels that the voluntary accreditation is one means toward accomplishing quality concrete.

To summarize, it is our opinion that the NVLAP program appears to be successful in accrediting laboratories, deserves our continued support and should be continued.

Sincerely,

Harold W. Gilley
Director of Education

HWG:jj

Copies to Howard Newlon, Jr.
George F. Leyh

CMA

CHEMICAL MANUFACTURERS ASSOCIATION

GERALDINE V COX, Ph.D.
Vice President
Technical Director

December 16, 1981

Dr. Jack Williams
Office of Product Standards Policy
Room 3876
Department of Commerce
Washington, D.C. 20230

Dear Dr. Williams:

Following up my letter of November 10, 1981 to Dr. Warshaw, I enclose our statement for publication in the proceedings of the November 16-17 Public Workshop on Laboratory Accreditation.

Sincerely yours,

Geraldine V. Cox

Enclosure

Formerly Manufacturing Chemists Association—Serving the Chemical Industry Since 1872.
2501 M Street, NW • Washington, DC 20037 • Telephone 202/887-1260 • Telex 89617 (CMA WSH)

STATEMENT
OF THE
CHEMICAL MANUFACTURERS ASSOCIATION
FOR
PUBLICATION IN THE PROCEEDINGS
OF THE
NOVEMBER 16-17, 1981
PUBLIC WORKSHOP ON LABORATORY ACCREDITATION

The Chemical Manufacturers Association (CMA) submits the following statement. CMA is a nonprofit trade association having 184 U. S. company members representing more than 90% of the production capacity of basic industrial chemicals within this country.

CMA believes that all laboratories carrying out specific tests or types of tests on chemicals or chemical products should demonstrate their competency to carry out these tests by adhering to the guidelines in one or both of two documents: (1) Organization for Economic Cooperation and Development's Principles of Good Laboratory Practice (Final Report of the Expert Group on Good Laboratory Practice, October 16, 1981), and (2) Guideline for Data Acquisition and Data Quality Evaluation in Environmental Chemistry (Analytical Chemistry 1980, 52, 2242-2249).

By "all laboratories", we mean all laboratories operated by federal, state, and local jurisdictions; and all in-house or contract service laboratories.

By "tests", we mean tests to determine performance, composition, physical properties, emissions, potency, etc.

Voluntary adherence to these guidelines would do much to ensure that data are universally understood and more uniformly reliable. Testing laboratories could verify their compliance with these guidelines in writing when necessary.

Following this practice would eliminate the need for, and cost of, a government inspection and auditing agency.

BUCKNELL

Department of Civil Engineering
Bucknell University
Lewisburg, Pennsylvania 17837

717-524-3653

December 16, 1981

Mr. James Bryson
Director of NVLAP
National Bureau of Standards
Washington, DC 20234

Dear Jim:

Enclosed are my thoughts on laboratory accreditation. Please feel free to use them as you see fit, including augmenting them if you wish. In particular you might wish to mention how long NBS has had the collaborative reference program for concrete and asphalt and how they have been responsible for the development of the Tuckerman and Whitemore strain gauges and the Hunter, Sigler and Brungraber devices for measuring slip-resistance.

No doubt there are many other contributions of which I am unaware. A stroll through the museum might prove fruitful for ideas.

Lots of luck,

Sincerely yours,

Robert J. Brungraber, Ph.D., P.E.
Presidential Professor of Civil Engineering

RJB:hbm
Enclosure

People have always sought protection from events beyond their control or their ability to recover from. For this reason serfs of the middle ages were willing to give up much of their freedom and income in return for the protection of the Lord against the outcome of wars, famines and plagues; and more recent generations have been willing to pay rather significant insurance premiums and/or relinquish some of their freedoms to the state in return for protection from fire, electrocution, explosion, floods, etc. Now, however, we American citizens are seeking ever more certain protection from ever more kinds of hazards. Under the impetus of lending institutions and Federal agencies we seek assurance that all components of a building will last, without maintenance, at least for the life of the mortgage. With the urging of the Congress we seek to improve the energy efficiency of our buildings and thus we wish assurance that the insulation and heating systems that we are encouraged to buy are good value. For these and many other reasons the performance of a large variety of products and appliances must be realiably measured. This in turn has increased the number of, and the demands on, the private and public testing laboratories.

In order to have confidence in the reliability of these performance measurements, we could either have them all made by a single central laboratory or else have the many noncentralized laboratories monitored by some organization that would assure the reliability of their work. Given our tradition of free enterprise the latter seems to be the more viable approach.

Given that a variety of laboratories; large and small, public and private, must be monitored for performance, how best can this be carried out. It would seem that the operative phrase here is "monitored for performance." Assessing the equipment and staff of a laboratory may serve to predict whether or not a laboratory can perform but only monitoring the actual performance will assure that it actually does perform. Also to provide standards for equipment and staff that would be sufficiently general to apply to all types and sizes of laboratories, without being excessively restrictive so as to unduly restrict new entries into the field, would require much on-the-site interpretation of rules, which is always a difficult problem. On the other hand a good test result is a good test result regardless of the size of the laboratory.

Clearly different techniques of monitoring reliability of test results will have to be employed on different products but surely adequate, economically viable methods can be devised. In the process, improved test methods can also be developed. It seems reasonable that this process of monitoring test procedures can best be carried out by one central organization, since to do otherwise would mean either (a) to have a second level of actual test monitoring which would clearly duplicate effort unnecessarily or else (b) to develop some means of assessing the reliability of a laboratory monitoring organization, large or small, new or well established, etc. strictly on the basis of staff and equipment. Just as for assessing actual test laboratories this would either introduce insurmountable problems of flexibility of standards or else would serve to make extremely difficult the entry of new organizations into the field of laboratory testing.

If a single central organization is to conduct this monitoring it should have the following attributes:

(a) The equipment and staff to perform tests of unimpeachable reliability.

(b) A record of this reliability.

(c) The facilities and interest for developing improved test methods.

(d) A record of maintaining standards and developing test methods.

The National Bureau of Standards has these attributes and has had a reputation of having them since its inception. In fact the circumstances that prompted the institution of NBS, the lack of standardization of fire hose fittings that exacerbated the Baltimore fire, was the need for standardization that only a central organization could effect.

Robert J. Brungraber
December 16, 1981

HARVEY SCHOCK
PRODUCT ASSURANCES CONSULTING
P. O. DRAWER 130
HADDONFIELD. N. J. 08033

December 16, 1981

Mr. John W. Locke, NVLAP Coordinator
Room 4709
U.S. Department of Commerce
WASHINGTON DC 20230

Re: PUBLIC WORKSHOP ON:

LABORATORY ACCREDITATION;
FUTURE DIRECTION IN THE UITED STATES
November 16-17, 1981, NBS, Gaithersburg MD.

The Workshop provided a real opportunity for improving both quality and productivity of laboratory performance. Unfortuately the presentations failed to address the true alternatives and to quantify proposed benefits for the petitions.

The development of systems and programs for evaluation and accreditation has been important and equally important has been the development of criteria for use in these areas.

As you know the American Society of Testing and Materials (ASTM) has Technical Committee E-36 on Generic Criteria for the Evaluation of Testing and Inspection Agencies. Although ASTM does not evaluate or accredit it does provide a voluntary consensus standards capability for the development of generic and specific criteria, test methods, and product standards both nationally and internationally.

I personally prefer to see this voluntary consensus standards capability continue and hereby submitted a TITLE and ABSTRACT for a presentation on November 16-17, 1981, as follows:

TITLE:

Voluntary United States Capabilities, Criteria, and Systems For Testing and Inspection Agency Evaluation and Accreditation.

ABSTRACT:

The United States is fortunate to have in its voluntary consensus standards system the capability to develop generic and specific criteria for evaluation and accreditation of testing and inspection agencies or activities. This co-exists with but is separate from the ability to develop standards for test and inspection methods, used in such evaluations and accrediations, as well as standards and test methods for the involved products and services.

What is needed is improved productivity by simplifying our systems, not the imposing of additional layers of approvals or oversights.

The present systems in the United States have evolved by the addition of special requirements on top of special requirements. Only recently has the Federal government realized the opportunities available through improving regulations by elimination and simplification.

Some of this opportunity is seen in recent Federal government requirements for Good Laboratory Practice in national and international areas.

Unfortunately it is presently impossible to obtain information the criteria used for specific evaluation and accreditation in all alleged public accreditation systems in the United States. This lack of availability constitutes a hardship for laboratories or producers desiring to tailor their systems for special evaluation or accreditation requirements.

This paper presents a summary of evaluation consderations. It identifies specific improvement opportunities for government, industry, and public. It provides a simplifed approach for improving our systems as replacement for formal accreditations.

It was my intent to offer a summary of criteria I have found important in internal company evaluation of its own testing laboratories. Obviously such internal practices are the most effective and efficient because they are installed and allowed to continue only as long as they add value for the company. Such has not always been the fact for externally invoked requirements or programs.

Unfortunately my paper was not accepted and was not presented at the Workshop. I did however have opportunity to make some quotations from the Abstract and to offer some comments at the Workshop.

I feel strongly that the real needs and purposes of evaluation and accreditation should be reviewed before any formal program is started. These should be reviewed on a periodic basis as the requirements and each program continues. A major part of such review must be the economics of costs and benefits.

Where there is a real need for requirements, and especially where there is any form of formal program, there must be constant evaluation of alternatives. Such alternatives must include consideration for elimination of ny such added requirements and programs with a return to normal non-formal activities.

In response to your solicitation for opinion on the Three Specific Questions, I offer the following on each of the THREE IDENTIFIED ISSUES:

1- Whether the Department of Commerce should cease its present role and substitute in its place a program to accredit organizations which, in turn, would accredit private sector testing organizations;

COMMENTS:

The Department of Commerce should not cease its present role as operator of the National Voluntary Laboratory Accreditation Program (NVLAP).

REASONS:

The Department of Commerce has demonstrated, with its National Voluntary Laboratory Accreditation Program (NVLAP), that is has the ability to develop measurement techniques for evaluation and accreditation of testing and inspection work for the benefit of commerce, government, and the public. These advanatges have been demonstrated in the THREE existing NVLAP Programs and in the work started under NVLAP for further specific programs to meet additional requests by government and industry.

The NVLAP work has demonstrated voluntary savings for various levels of government, for industry, and for the public through raising the acceptability of laboratory services without introducing additional hardships on the evaluated parties.

The NVLAP work should continue rather than moving into the accrditation of private organizations especially since the Department of Commerce and the National Bureau of Standards do not presently have the capability to remove themselves from actual technical measurement, by limiting to overview of management systems and programs for only the evaluation and accreditation areas. Such a move out of technical measurement and into management areas would be beyond the present charter and capabilities of the National Bureau of Standards and would be contrary to the present desire of the Federal government for disengagement from entering into new areas such as private business management reviews.

2- What, if any, additional measures should be taken to assure that an effective U.S. presence remains in international laboratory accreditation activities, including bilateral agreements:

COMMENTS:

There should be no additional measures taken by the Federal government. The voluntary standards systems, nationally and internationally, presently has the means to develop voluntary consensus positions. These should continue to be related to the voluntary systems for development of standards used for materials, products, services, test methods, terminology, and specifications.

Presently there exist many bilateral and multilateral agreements relating to laboratory areas outside of government. Generation of future agreements are best developed on bilateral basis, even though there was absence of papers at the Workshop discussing the many existing bilateral agreements and systems. In fact the paper proposed by the undersigned was not accepted for presentation, apparently because it questioned seriously the need for initiating a new single Federal oversight approach to recognition of laboraotry evaluation and accreditatiion systems.

3- What action, if any, can be taken by the private sector and/or the government to reduce the proliferation of inspections and paperwork arising from duplicative accreditatiion activities within the United States:

COMMENTS:

The obvious answer to this is for the Federal government to participate in the excellent opportunities of the voluntary standards systems of the United States. This should and must be the route used for the development of any new requirements. Such requirements must and will represent the best available thoughts of the private sector and as such should permit direct use without the imposition of extra steps or systems. Naturally the private sector must participate in such work and if government, at all levels of Federal, State, and local, participates in the voluntary system there should be the best value obtained for all parties.

Thank you for permitting this opportunity for submission.

Cordially,

Harvey Schock

cc: Mr. James O. Bryson
Chief- Office of Testing Laboratory Evaluation Technology
National Bureau of Standards
WASHINGTON DC 20234

CERTIFIED *Testing* LABORATORIES, Inc.
PHONE (404) 226-1400 · 1105 RIVERBEND DRIVE · P. O. BOX 2041 · DALTON, GEORGIA 30720

December 17, 1981

Dr. Jack Williams
Office of Product Standards Policy
Room 3876
Department of Commerce
Washington, DC 20230

Dear Dr. Williams:

This letter is in reference to the NVLAP function of the Department of Commerce and the proposal to substitute a private sector agency to fill that function.

The first consideration, from our point of view, is whether or not any central accreditation program is desirable.

We are currently participants in both the insulation and carpet LAP's. We felt the insulation LAP was a badly needed program. The industry portrayed an image that appeared to lack credibility. I believe NVLAP helped everyone. The carpet LAP benefits were less obvious. However, even in the carpet area, we have found accreditation through the Bureau of Standards helpful in our relations with agencies which, otherwise, might have required a more formal presentation.

As an independent testing laboratory, our basic commodity is credibility. Credibility includes competence and lack of bias, or integrity. The NVLAP effectively attests to the competence. Additionally, it excludes those whose equipment, staff and procedures are inadequate.

We, therefore, find the national program helpful. We would suggest that it may be even more helpful if the accreditation agency were designated as NBS, rather than DOC, since NBS is the more recognizable and prestigious name in the technical community, both here and abroad.

For the same reasons we recommend the use of the NBS name, we do not believe a private sector accreditor will be effective. Whereas we currently see diminishment in separate accreditation requests, we do not believe any private sector agency will equal the stature of NBS.

Cordially,

CERTIFIED TESTING LABORATORIES, Inc.

John H. Frank, President

cc: Dr. Stanley I. Warshaw, Director
Office of Engineering Standards
National Bureau of Standards
Department of Commerce
Washington, DC 20234

ETL Testing Laboratories, Inc.

Industrial Park Cortland, New York 13045 Telephone 607-753-6711 TWX 510 252 0792

Earl J. Gmoser
Vice President

December 17, 1981

Dr. Jack Williams
Office of Product Standards Policy
Room 3876
Department of Commerce
Washington, DC 20230

RE: Comments - NVLAP Public Workshop

Dear Dr. Williams:

Enclosed are comments by ETL Testing Laboratories, Inc. in response to Public Workshop on Laboratory Accreditation; Future Directions in the United States which we ask be included in the post workshop commentary for your review and inclusion in the published record.

We believe that the workshop was helpful in the deliberations surrounding NVLAP's future activities, and we look forward to reviewing the published proceedings when they become available.

Very truly yours,

Earl J. Gmoser

EJG/mt

Enclosure

cc: J. Tucker

COMMENTS RELATIVE TO PUBLIC WORKSHOP ON LABORATORY ACCREDITATION; FUTURE DIRECTIONS IN THE UNITED STATES

by

ETL TESTING LABORATORIES, INC., CORTLAND, NY

ETL Testing Laboratories, Inc., Industrial Park, Cortland, NY is an independent, commercial testing laboratory with over 85 years of service to industrial and governmental organizations. It operates 30 industry-wide certification programs in addition to its regular testing operations. One of the certification programs is the HUD UM44C Program for carpets, and for which NVLAP has a LAP for carpet testing. Two pending LAP's, in acoustics and possibly structural testing of windows and doors would serve two other of ETL's certification programs for Air Conditioning and Refrigeration Institute and Architectural Aluminum Manufacturers Association, respectively.

ETL is supportive of the NVLAP and has had good experience with the carpet LAP. If that same quality is continued on into other LAP's, then there is a good reason for NVLAP to be continued in its new home at the National Bureau of Standards. There is a need for accreditation of laboratories, not all, but certainly in those industries where there currently exists more than one approval agency or requirement for the same product or where questionable data are apparent.

No LAP should be developed unless there is substantial need for it for the foregoing reasons, and the request for it must be on a voluntary basis, not by government directive. The only exception to the latter would be where no private sector group can bring order to a suspect testing service.

Additionally, no LAP should ever be developed purely to change the market position of laboratories. For example, commercial laboratories must frown upon the development of a LAP mainly to permit a captive laboratory to be accepted for testing where formerly that laboratory's testing was not acceptable because it was owned by the manufacturer of the product being tested. We have commented on this subject before to NVLAP's John Locke. We have already experienced signs of reduction in testing services because of several giant captive laboratories now doing the testing of their own product (and for others as well) for acceptance.

As a matter of fact, NVLAP's first LAP and a pending one were spearheaded by one large manufacturer whose production and testing represent a major portion of their industry's products. There is no question that the manufacturer's laboratory has benefited at the expense of commercial laboratories by broadening the position of acceptance.

The mantel of independence is most cherished by us, and NVLAP should not pass that on merely because a captive laboratory can perform a test. Please understand, we are not saying that NVLAP is doing that by design; it is simply that motivation must also be considered when requests for LAP's are promulgated.

At this time we do not believe that NVLAP should become an accreditor of accreditating agencies. Such an effort would possibly assign too much authority to NVLAP which as a part of government might be led to drift to to the level of a self-serving bureaucracy. Its present governmental status is beneficial because operating in voluntarily developed activities, it lends the prestige of government in the accreditation of a laboratory to perform a test. That "endorsement" would also appear to compliment the need to have nationally accepted testing for purposes of intra and international trade.

Our experience as we work toward gaining approval as a nationally accepted laboratory shows that we have been often thwarted by barriers to trade by local, municipal and state regulations sometimes far more difficult to overcome than those in international activities. More needs to be done to make the acceptance by government of good laboratories less restrictive, and to lessen the variety of the requirements by different jurisdictions for the same service. Hopefully, an effort can be mounted by NVLAP to get its partners in government to accept its efforts as being responsible and thereby eliminate the hundreds of approval applications strewn in the path to national acceptance of a laboratory. Indeed, this is one where NVLAP would seem to have good reason to be in existence.

Many industries have developed their own accreditation systems and one example is the steel industry. Their public statements (made at the NVLAP workshop) is to the effect that they don't need outside "interference" in accreditation of their some 1500 plant laboratories. If their system has proven successful and the data are without challenge, then there is no need for NVLAP, or any other accreditor, to duplicate the service. The idea of NVLAP being the accreditor for all industries would seem to be not only limiting the freedom of choice, but also bring NVLAP to an almost uncontrollable level of authority over the activity of the laboratory industry. The costs to the industry, as well as to the tax payer, would surely be unacceptable.

ETL's recommendation with respect to the questions raised in the recent workshop is that there appears to be a need for NVLAP's services in certain areas, that they should not be all encompassing and LAP's should be developed only in those industries, or segments thereof, voluntarily requesting them, and that some effort should be made to encourage government to also request LAP's where there exist cumbersome duplicative requirements in their operations. Foremost in NVLAP's continuance should be an effort to contain costs both to the user and the taxpayer, and that any funds expended not serve to shift the traditional position of commercial versus captive laboratories in the marketplace.

As long as NVLAP's efforts remain in the voluntary sector, it plays a proper role in the standardization and maintenance of quality in those areas of the testing industry requesting its services; if such role should shift to a regulatory one (which would be unacceptable) then it will no longer encourage the continuing technical input of those it serves, thereby reducing the quality of the entire accreditation process.

GENERAL DYNAMICS
Fort Worth Division
P.O. Box 748, Fort Worth, Texas 76101 • 817-732-4811

273-81-427
17 December 1981

Mr. John W. Locke
NVLAP Coordinator
Department of Commerce, Room 4709
Washington, D. C. 20230

Dear John:

In your letter of November 30, 1981 you referenced the Federal Register notice and the meeting at NBS. I would like to comment on the issues raised in your letter.

1. Whether the Department of Commerce should cease its present role and substitute in its place a program to accredit organizations which, in turn, would accredit private sector testing laboratories.

   I do not believe the Department of Commerce should cease its present role in accrediting laboratories. Probably the main reason the NVLAP program was instituted was to provide a competent and recognized body to administer the Laboratory Accreditation Program. Since many U.S. companies are engaged in international business it becomes more important that a recognized agency such as the U.S. Government be the accrediting source.

   Another reason is great problems existed with many accrediting bodies being semi-recognized by different organizations. If the Department of Commerce wants to change its role, my recommendation would be to strengthen it greatly rather than abdicate its responsibilities by simply accrediting other accreditors.

   I, personally, would like to see these other accrediting agencies go out of business and the entire task be accomplished by the Department of Commerce.

2. What, if any, additional measures should be taken to assure that an effective U.S. presence remains in international laboratory accreditation activities, including bilateral arrangements.

   I don't know of any additional measures that need to be taken for International Laboratory Accreditation. I believe that ILAC is progressing in the right direction. I wish there was some method of making things happen faster, since I am very much a neophyte in international affairs I don't have any recommendations.

273-81-427
17 December 1981
Page 2

3. What action, if any, can be taken by the private sector and/or the government to reduce the proliferation of inspections and paperwork arising from duplicate accreditation activities within the United States.

   I believe the answer to No. 3 is essentially the same as No. 1 and that is if some agency, hopefully the Department of Commerce, could become "THE" accrediting agency, then there would not be a need for other inspections by the many varied accrediting agencies.

Sorry I was not able to attend the Workshop at NBS November 16-17.

Sincerely,

J. C. Herr
Chief of Process Control

JCH:cl

BUILDING OFFICIALS & CODE ADMINISTRATORS INTERNATIONAL, INC.

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STAFF
Executive Director
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Deputy Executive Director
PAUL K. HEILSTEDT, P.E.

December 17, 1981

Mr. John W. Locke
NVLAP Coordinator
Department of Commerce
Room 4709
Washington, D.C. 20230

Dear Mr. Locke:

We recently had the opportunity to review your memorandum of November 30, 1981 regarding the Workshop on Laboratory Accreditation. BOCA was not able to attend the November 16 and 17 workshop but would like to comment on the three main issues identified in the workshop and repeated in your memorandum. Our comments are as follows:

1. The Department of Commerce should cease its present role in laboratory accreditation and rely on the private sector to perform the accreditation function. While the advantages of laboratory accreditation on a national scale are obviously attractive, there is no reason why the process must be a governmental function. The private sector has the organizations and capabilities in place to accomplish this task more economically and expeditiously.

2. The Department of Commerce should retain its status as the international liaison for laboratory accreditation. While the submittal to American code officials of test results generated by foreign laboratories is becoming more prevalent, a mechanism should be generated to facilitate the approval of the results of tests conducted by foreign laboratories as well as representation to the international community.

REGIONAL OFFICES

3021 East Dublin-Granville Road
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3. Coordination of laboratory accreditation efforts can be generated through voluntary efforts in the private sector. A process much like that used for the coordination of standards by the American National Standards Institute can be developed. It is essential that a nationally recognized system of laboratory accreditation be developed as opposed to a multiplicity or duplication of systems.

Please contact us if you have any questions or comments.

Very truly yours,

Paul K. Heilstedt, P.E.
Deputy Executive Director

PKH/dlj

U.S. Department of Labor

Occupational Safety and Health Administration
Washington, D.C. 20210

Reply to the Attention of:

17 DEC 1981

Mr. John W. Locke
NVLAP Coordinator
Department of Commerce
Room 4709
Washington, D.C. 20230

Dear John:

This is in response to your request for comments on the proceedings of the NBS "Workshop on Laboratory Accreditation." These comments will address remarks made during the proceedings regarding OSHA's laboratory accreditation program and AALA. It is requested that the following comments be included in the record of the workshop proceedings.

In many of the consensus standards adopted by OSHA at its inception, there is the requirement that certain products be approved by nationally recognized testing laboratories, such as Underwriters Laboratories, Inc. and Factory Mutual Engineering Corporation. This system of approval of products, critical to safety, has been in operation nationally for many years prior to OSHA. However, in order to accredit additional qualifying test laboratories, OSHA promulgated the regulation, 29 CFR 1907, Accreditation of Testing Laboratories, Criteria and Procedures.

Although OSHA has not implemented its laboratory accreditation program, it has held two public hearings and received numerous comments on the regulation. Based on those hearings and comments, OSHA has pursued solutions to certain technical and administrative problems associated with the program. The solutions sought had to be consistent with the need for a program whereby other laboratories can be accredited, in addition to those presently recognized in OSHA regulations.

As part of the study by OSHA to seek solutions to some of the aforementioned problems, the American Association for Laboratory Accreditation (AALA) was given a contract to develop an accreditation program which would satisfy OSHA's needs, based on 29 CFR 1907. However, there is no existing plan to utilize criteria developed by AALA, since OSHA is preparing to review all of its existing regulations, including 29 CFR 1907, in accordance with the Regulatory Flexibility Act. The Act, which went into effect in January 1981, requires agencies to determine the impact of their regulations on small business, organizations, and governmental jurisdictions. The Act also requires that agencies review all their regulations within ten

years. 29 CFR 1907 will be subjected to this review in 1983. A formal notice will appear in the Federal Register announcing the review, and comments will be requested from interested parties. When this evaluation is completed, OSHA will determine the future direction of 29 CFR 1907.

Sincerely,

P.J. Cattafesta
Safety Engineer
Office of Mechanical Engineering
Safety Standards Programs

TIMA
THERMAL
INSULATION
MANUFACTURERS
ASSOCIATION

7 KIRBY PLAZA, MT KISCO, N Y 10549 914/241-2284

18 December 1981

Mr. J. W. Locke
NVLAP Coordinator - Room 3876
U. S. Department of Commerce
Washington, DC 20230

Dear Mr. Locke:

With respect to laboratory accreditation TIMA, is in opposition to the separation of the program from the Department of Commerce.

The present NVLAP program has international credibility and acceptance and is being used by local, state and federal authorities.

Sincerely,

J. M. Barnhart
Executive Director

JMB:emf

NRMCA
NATIONAL
READY MIXED
CONCRETE
ASSOCIATION

900 Spring Street, Silver Spring, Maryland 20910
Telephone: (301) 587-1400

December 23,1981

Mr. John W. Locke
NVLAP Coordinator
Department of Commerce
Room 4709
Washington, D. C. 20230

Dear John:

Enclosed is a letter from Ralph Vencill commenting briefly on the November Workshop. It should be a part of the record if possible.

Yours truly,

Richard D. Gaynor

Richard D. Gaynor, Vice President
of Engineering and Research

RDG:sfh
enc.

MATERIAL SERVICE CORPORATION
300 WEST WASHINGTON STREET · CHICAGO, ILLINOIS 60606 · 312/372-3600

October 14, 1981

National Ready Mixed
Concrete Association
900 Spring Street
Silver Spring, Maryland 20910

Attn: Mr. Richard D. Gaynor

Re: Workshop on Laboratory
Evaluation - November,
16-17, 1981
Gaithersburg, Maryland

Dear Dick:

Since I won't be able to attend the above referenced meetings on laboratory evaluation, I would like to express some of my opinions on the N.V.L.A.P. Program to date.

As you recall, in the beinning, our industry felt the need for uniform testing, had reached a point where we had to have a program that would improve the reliability and credibility of all parties involved in the testing of concrete.

The administration, implementation and funding of such a program was discussed at length and it was decided that the Department of Commerce would be the most logical agency to operate the program.

Now that the N.V.L.A.P. Program is operating, my observations and comments are:

1. The original application form and instructions could and should be more simple, more concise and to the point. I am afraid a lot of potential members take one look and say, is it worth the effort.

2. The sample manual prepared by National Redi-Mix for the N.V.L.A.P. Program should be a definite aid for new members.

3. I feel very comfortable with the C.C.R. L. doing the inspection for the N.V.L.A.P. accreditation.

They are a nationally recognized agency with very high credibility, thus lending itself to uniform application of the requirements for the N.V.L.A.P. Program.

- continued -

4. I am not in favor of changing any of the accreditation activities to the private sector at this time, but I do think the private sector should get behind this program and make it a viable program, for the need is certainly there.

Sincerely,

Ralph Vencill
Ralph Vencill
Manager of Technical Services

RV/dz

MICROWAVE ASSOCIATES, INC., BURLINGTON, MA 01803, TELEPHONE (617) 272-3000, TWX 710-332-6789, WESTERN UNION FAX, TELEX 94-9464

December 21, 1981

Department of Commerce
Room 4709
Washington, D.C. 20230

Attention: Mr. John W. Locke
NVLAP Coordinator

Dear Mr. Locke:

The NBS sponsored Workshop on Laboratory Accreditation held on November 16th and November 17, 1981, provided an interesting forum for discussion by concerned individuals and organizations. The following are my questions, thoughts, and opinions addressing the national status of laboratory accreditation in a specific area of interest - metrology.

Who will be conducting the laboratory accreditation process of a metrology laboratory? Obviously, one would have to be an expert in the field and be completely free from personal bias. Their competance and integrity must have absolute acceptance.

How would one conduct the laboratory accreditation process? What format or criteria would one use? MA-COM's standards and calibration laboratories are surveyed by numerous government and customer "teams" who use a variety of formats and procedures. It is not unusual to have several audits in one week. Could there be "universal" acceptance of one "formal" audit or would there just be another audit added to the list? My company, as well as many other companies I have talked with, must submit to "ongoing in-house" DCAS audits as well as periodic surveys by regional DCAS personnel. These surveys conducted by the regional DCAS personnel are quite extensive and last several days. Yet this fact does not diminish the increasing number of other customer's audits to certify that our laboratories comply to acceptance standards.

Is there a need for another laboratory accreditation procedure for a metrology laboratory? This question could be asked first' yet, the preceding questions should be answered before a conclusion on need is finalized. Expressing my opinion as an individual, not as a representative of MA-COM or any other organization, one should analyze and evaluate existing procedures and formats to determine if there are

A COM COMPANY

12/21/81
Sheet 2 of 2

re: Workshop on Laboratory Accreditation

government "accrediting" agencies already in place (eg: DCAS) who are responsible for certifying the capabilities and creditability of supplier laboratories. Let's identify, evaluate, and improve existing systems where we can before creating new or additional ones.

I attended the Laboratory Accreditation workshop on behalf of the National Conference of Standards Laboratories (NCSL) as well as MA-COM. Mr. John Lee, President of NCSL, asked that I (as Chairman of the Laboratory Evaluation Committee) monitor and report on the workshop. I will give my report at the January 1982 NCSL Board of Directors Meeting in Florida. Any formal conclusions by the National Conference of Standards Laboratories will be forthcoming after that meeting.

I look forward to a continuing discussion on this important topic of laboratory accreditation. As a twenty year metrology "veteran", Past President of the National Conference of Standards Laboratories, and a co-author of NCSL's approved Recommended Practice on Evaluating Calibration Laboratories, I offer my services to you. Please call on me.

Sincerely yours,

MICROWAVE ASSOCIATES, INC.

Ronald E Kidd

Ronald E. Kidd

CONCRETE GROUP: 155 East 21st Street / P.O. Box 4667 / Jacksonville, Florida 32201 / (904) 355-1781
FLORIDA ROCK INDUSTRIES INC Mining, Ready Mixed Concrete, Construction Products and Transportation

January 28, 1981

Mr. John W. Locke
NVLAP Coordinator
U.S. Department of Commerce
Room 4079
Washington, D.C. 20230

Dear Mr. Locke:

This letter is in reference to the current discussion of the merits of the NVLAP for Testing of Freshly Mixed Field Concrete. In our operational area (Florida, Georgia, Virginia) we and other members of the concrete industry continue to observe grave deficiencies in the testing of concrete. With the current trend toward higher concrete strengths for more economic structural designs, the proficiency in testing concrete and the availability of suitable equipment assume particular significance.

This was illustrated by a recent occurrence in the Central Florida area, with two laboratories determining substantially different strengths on the same 6000 PSI concrete used in critical column construction. It implied that,either, one laboratory under-represented the actual strength of the concrete, thereby necessitating expensive verification tests, or that testing by the other laboratory was biased toward higher-than-actual strength indications, thereby favoring the acceptance of substandard concrete.

This experience emphasizes the need for laboratory evaluation because of the impact of testing deficiencies on the public domain, either through unnecessarily increasing the cost of construction which, in one form or another, is borne by the consumer; or through covering up of substandard construction, which may result in a direct danger to the general public.

As illustrated by the above example, laboratory qualifications for testing concrete hinge on accurate performance of basic methods of test. It has been our experience that excellent professional credentials at the executive level even of highly reputable laboratories do not necessarily indicate a corresponding excellence at the technician level.

An accreditation system provides a significant service only if it examines the proficiency of laboratory personnel in the basic testing methodology of concrete; if it requires an internal quality control system with appropriate documentation; if accuracy of strength tests is periodically verified through between-laboratory tests of duplicate specimens from the same concrete sample; and if complaints regarding malpractices are handled by a review body which is removed from the in-group context that accreditation by peers would

represent. These provisions are presently part of the NVLAP accreditation system.

It appears questionable whether an accreditation system advocated by the private sector will include similar provisions. In considering the relative merits of NVLAP vs. private sector accreditation, other factors support the continuation of NVLAP:

(1) Impartiality of inspection inherent in an NBS-affiliated program.

(2) Optimum preservation of the public interest through removal of accreditation from the private sector.

(3) Existence of a viable inspection system (NBS-CCRL).

(4) General recognition and acceptance by an uninformed public of laboratory accreditation, if implemented by the National Bureau of Standards.

Yours very truly,

Martin Mittelacher

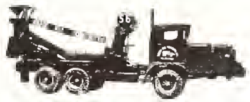
Martin Mittelacher
Director of Technical Services

MM/mm

READY MIX CONCRETE, INC.

POST OFFICE BOX 1909
CAROLINA PUERTO RICO 00630

CABLE ADDRESS READYMIX
SAN JUAN PUERTO RICO
TELEPHONE: 769-3030



December 28, 1981

Mr. John W. Locke
NVLAP Coordinator
Department of Commerce
Room 4709
Washington, D. C. 20230

Dear Sir:

We wish to express to you through these lines our interest and concern for the continuation and expansion of NVLAP and the Concrete Laboratory Accreditation Program.

We believe that this program should be very significant for the construction industry and specifically for the ready mix concrete industry. We respectfully believe that the same will provide both the industry and the public with a correct way of identifying qualified laboratories. It should also motivate laboratories to improve the quality of their services.

Improved concrete testing would definitely reduce the cost of concrete and would also provide a better protection to the public and to workers from structural failures while improving the service life of structures and reducing their maintenance and replacement.

Trusting that our request merits your consideration, we remain

Respectfully yours,

READY MIX CONCRETE, INC.

Aureo W. García
President

mm

CONROCK

CONROCK CO.

3200 SAN FERNANDO ROAD / P.O. BOX 2950 / LOS ANGELES, CALIFORNIA 90051 / (213) 258-2777

December 30, 1981

John W. Locke
NVLAP Coordinator
Department of Commerce
Room 4709
Washington, D.C. 20230

Dear Mr. Locke:

Conrock Co. Laboratory has just received their accreditation under the provisions of the National Voluntary Laboratory Accreditation Program (NVLAP).

Prior to our application, we obviously felt the need for this accreditation program, however it was not until we got into the actual preparation of our program and the CCRL Inspection that we fully appreciated the need for NVLAP.

Our management, and our customers, now know that our laboratory is equipped and qualified to perform our function properly. More important however, our laboratory technicians have the knowledge that their own procedures and techniques have been evaluated and found to be proper. The entire specturm of our in-house testing has been improved as our technicians take pride in the fact that we have received this accreditation.

Based on the above experiences we would urgently request the continuation of this voluntary program.

Sincerely,

Robert W. Floyd
Assistant Manager
Testing Laboratory

cc: Richard D. Gaynor

READY MIXED CONCRETE · ROCK AND SAND · LIGHT WEIGHT CONCRETE

STANDARD SAND & GRAVEL COMPANY

THIRTY-FOURTH AND MARKET STREETS · PHONE (304) 233-2710

WHEELING, WV 26003

December 31, 1981

Mr. John W. Locke
NVLAP Coordinator
Department of Commerce
Room 4709
Washington, DC 20230

Dear Sir:

It is essential, that all those involved in the placing of concrete, have a qualified concrete laboratory perform the acceptance testing.

Accredited laboratories are a necessity and we do not believe that the industry would be able to police itself.

We, therefore, urge that the National Voluntary Laboratory Accreditation Program be continued.

Very truly yours,

STANDARD SAND & GRAVEL COMPANY

D. C. Dickson
President

DCD/dm

Keeler
THE WALT KEELER COMPANY, INC. 826 E. LINCOLN, P.O. BOX 197 WICHITA, KANSAS 67201

December 31, 1981

Mr. John W. Locke
NVLAP Coordinator
Department of Commerce
Room 4709
Washington, D.C. 20230

Dear Mr. Lock:

Ready mixed concrete producers (manufacturers) support the need for laboratory accreditation. In commerical concrete construction acceptance testing is performed by commercial laboratories, but there are no objective standards for the quality assurance and quality control of these laboratories. The operations are small and highly competitive. Too often improper testing procedures and errors result in low strength test results which must be investigated to determine if remedial action is needed in the structure. These delays disrupt the construction process.

Accreditation also provides a standard by which the concrete producers own laboratory staff can be measured and thereby gain recognition that is denied them in the absence of an objective detailed standard for performance.

The ready mixed concrete producers manufacture concrete and are responsible for the quality of the material delivered to the jobsite. Concrete is a unique material in that it cannot be tested before the material is actually used in a structure. Although there is a valid testing methodology, the concrete construction industry is much fragmented and few concrete laboratories have well organized quality control - quality assurance programs. There is a need to identify well organized professional laboratories and improve the quality of testing services available.

Since testing is often a bid item the contractor often selects the lowest bid or even decides to make the cylinders with his own labor and deliver them to the laboratory for testing. About half of all cylinders are contractor made. Since the required capital investment for concrete testing is modest and no high level of scientific knowledge is required there are lots of backyard, garage and basement labs in the industry.

The NVLAP process uses general and specific criteria that incorporate the substance of E 548 and apply it to specific products or groups of test methods. This accreditation provides, for the first time in concrete testing, a way by which a user of laboratory services can identify and specify the quality of the service desired or expected.

CONCRETE MIXED IN TRANSIT SAND • BUILDING MATERIALS • CRUSHED STONE
TELEPHONE (316) 265-0615

Concrete producers support accreditation for two principal reasons. First, too often current practices and competitive conditions produce an unacceptably low standard of testing quality. Accreditation provides a method for evaluating the capability of the concrete producers quality control and testing organization.

The NVLAP Program is the best thing that has happened to the concrete industry for a long time.

Sincerely,

THE WALT KEELER COMPANY, INC.

Earl F. Callison, Jr.,
President

EFC:lsw

AMERICAN ASSOCIATION
FOR LABORATORY ACCREDITATION
1001 North Highland Street, Suite 101, Arlington, Virginia 22201 • 703/528-0072

December 29, 1981

John W. Locke
NVLAP Coordinator
Office of Product Standards Policy
US Department of Commerce
Washington, D.C. 20230

Dear John:

This is in response to your letter of December 11, 1981, asking for additional comments to be added to the proceedings of the seminar held on November 16 and 17 at the National Bureau of Standards.

During the presentation made by Lou Rossi, Chairman of AALA, it was noted that AALA expected several laboratories to commit either to accreditation or to membership in AALA. Since the conference, 32 laboratories have committed to accreditation and 20 laboratories have committed to membership.

It would be most appreciated if you would include this information in the record of conference proceedings.

Sincerely,

John

John F. Magnotti, Jr., Ph. D.
Executive Director

JFM/cmr

Transit-Mix
CONCRETE AND
FOUNDATION COMPANY

D. PAT WHEAT
O. P. WHEAT, JR.
WARREN GOEHRINGER

2255 LOUISIANA AVENUE
P. O. BOX 5187 BEAUMONT, TEXAS 77702
AREA CODE 713 835 4933

January 5, 1982

Mr. John W. Locke
NVLAP Coordinator
Department of Commerce
Room 4709
Washington, D.C. 20230

Dear Mr. Locke:

As a producer of Transit Mixed Concrete we are concerned that the laboratories that are hired to test our product are qualified with respect to their people and their equipment. Since Transit Mix Concrete is usually the first major structural material that goes into, or under, a structure or building it is imperative that competent and accurate testing be accomplished. We feel you will know all the reasons for this and will not take time here to detail them.

The reason we support the NVLAP program is because of the possibility of conflict of interest in any laboratory group or industry group that funds its own program for establishing standards and monitoring them when these standards apply to themselves.

We do not support more and more federal spending and would encourage this program to become self supporting as planned, but under the guidelines set out by NVLAP.

Thank you for your consideration.

Yours very truly,

Warren Goehringer

Warren Goehringer

WG:wv

ERNST FUEL & SUPPLY CO.

"READY MIXED CONCRETE"

EAST SIDE PLANT (MAIN OFFICE)
23055 GROESBECK HWY.
CORNER 9 MILE ROAD
WARREN, MICHIGAN 48089
LAKEVIEW 7-1200
PRESCOTT 5-7200

December 31, 1981

Mr. John W. Locke
NVLAP Coordinator
Department of Commerce, Room 4709
Washington, D.C. 20230

Dear Mr. Locke:

It has come to our attention that due to budgetary considerations and pressure from competing organizations, NVLAP may be severely restricted in growth or dropped entirely.

As a member of the National Ready Mixed Concrete Association and a responsible supplier of concrete to the Detroit Metropolitan area, we are deeply concerned that such a potentially valuable service to the purchasers and users of concrete could be terminated before its true worth can be established.

It is our observation that in Michigan, for example, the concrete LAP has been largely ignored. We continue, as do the purchasers and users of our product, to suffer unnecessary costs directly attributable to poor performance by independent testing laboratories. Suggestions to these labs that they participate in NVLAP bring defensive responses doubting the need for them to certify their capabilities. Yet these same firms vigorously market a "professional" image to the owners and constructors. This enigma has persisted far too long.

What NVLAP needs now is better promotion, not cut-backs. If the federal government would insist on NVLAP approval for testing firms bidding on federal work, it could be a step toward encouraging independent laboratories to conduct their business in a more responsible manner.

We intend to recommend to our Michigan Ready Mixed Concrete Association that a 1982 priority should be vigorous promotion of NVLAP, the concrete LAP in particular.

Yours truly,

ERNST CONCRETE & SUPPLY CO.

Thomas Adams

Thomas Adams

WEST SIDE PLANT (INKSTER)
29001 MICHIGAN AVE.
EAST OF MIDDLEBELT
INKSTER, MICHIGAN 48141
PARKWAY 1-0422
LOGAN 3-6560

TA/ab

cc: Richard D. Gaynor, National Ready Mixed Concrete
900 Spring Street
Silver Spring, Maryland 20910
James R. Murner, Michigan Ready Mixed Concrete
1173 Trowbridge Road, East Lansing, MI 48823

DOWNRIVER PLANT (BROWNSTOWN)
20060 SIBLEY RD.
WEST OF ALLEN
WYANDOTTE, MICHIGAN 48192
AVENUE 5-1000

DOW
DOW CHEMICAL U.S.A.

MIDLAND, MICHIGAN 48640

January 11, 1982

Mr. John W. Locke, Coordinator
National Voluntary Laboratory Accreditation Program
Office of Product Standards Policy, Room 3876
U.S. Department of Commerce
Washington, D.C. 20230

Dear Mr. Locke:

Thank you for your phone call of last week. I do believe it is necessary for the National Bureau of Standards to have a role in the accreditation segment for standards in the United States and on a worldwide basis. This, perhaps, can be best achieved by the National Bureau of Standards serving as a peer reviewer in questions of doubt or dispute. While this concept is not complete, I believe it can be developed to the satisfaction of all.

Sincerely,

Robert W. Belfit, Jr.
Methods and Standards
Quality Assurance
2030 Dow Center

jl

AN OPERATING UNIT OF THE DOW CHEMICAL COMPANY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JAN 15 1982

John W. Locke
National Bureau of Standards
Technology Building B-06
Washington, D.C. 20234

Dear Mr. Locke:

In July 1981, the National Bureau of Standards (NBS) and the Nuclear Regulatory Commission (NRC) signed an Interagency Agreement for the development of a laboratory accreditation program for personnel dosimetry processors by the National Voluntary Laboratory Accreditation Program (NVLAP). This agreement relates to a regulatory program, being developed by the NRC staff for Commission approval, which would require licensees performing personnel monitoring in accordance with NRC regulations to obtain the services of personnel dosimetry processors accredited by NVLAP.

NVLAP and NRC staff personnel have worked together and with representatives of other agencies and industry, including dosimetry processors, in developing this program. NVLAP personnel have been sensitive to accomplishing this within an accelerated timeframe because of the need for this program and its public health and safety implications as documented by NRC.

The program will enable the NRC with minimum financial and technical resources to improve personnel dosimetry processing performed for workers at NRC-licensed facilities. The operational phase of this program will begin in the fall of 1982 and will be designed to enable the program to be self-supporting from fees assessed to processors who participate.

NVLAP provides NRC with an important mechanism for third-party evaluation of the performance of personnel dosimetry processors. It is possible that NRC's current use of NVLAP will be expanded in the future to include other areas such as bioassay laboratory accreditation, health physics instrumentation certification, and environmental monitoring. The services available from NVLAP that are not currently available from other Government agencies, or in the private sector, are of great importance to the NRC.

In November 1981, NVLAP sponsored a two-day workshop in response to two proposals for major changes in NVLAP. The first request was from the American Council of Independent Laboratories, Inc. (ACIL), which advocates the transformation of the NVLAP program from one which directly accredits laboratories to one which would accredit private sector organizations which, in turn, would do the actual accreditation of individual laboratories. The second proposal was from the American Association for Laboratory Accreditation (AALA). AALA recommends the transformation of NVLAP responsibilities as in the ACIL proposal, and also recommends the transfer of present NVLAP functions to the private sector. NRC personnel present at this workshop were concerned about the lack of information from AALA or other private sector organizations concerning details of their respective accreditation procedures, i.e., information concerning criteria for accreditation, appeal mechanisms, consideration of public comments, and the ability of AALA or other private sector organizations to develop accreditation programs for specific areas of need such as test method accreditation as currently exists under NVLAP.

The availability of acceptable third-party accreditation programs is of considerable value to the NRC. Our plans for the future include additional applications of this approach in order to assure competence in activities affecting radiation protection. For these reasons we want to emphasize the importance to us of continuity in the availability of services such as those offered by NVLAP. If a decision is made to accept either the ACIL or AALA proposals, we believe the Department of Commerce should continue the existing NVLAP program until AALA, or another private sector organization, has fully demonstrated its capability to conduct accreditation programs in a manner acceptable to the NRC and other organizations presently using NVLAP programs.

Sincerely,

Karl R Goller

Karl R. Goller, Director
Division of Facility Operations
Office of Nuclear Regulatory Research

BLUE ROCK
INDUSTRIES
58 Main Street
WESTBROOK, MAINE 04092
Tel. 854-2561

February 1, 1982

John W. Locke
NVLAP Coordinator
Department of Commerce
Room 4709
Washington, D. C. 20230

Re: Concrete NAVLAP

Dear Mr. Locke:

I take this opportunity to urge retention of the concrete NAVLAP which I understand is being resisted by some testing laboratory trade groups.

I am speaking as a producer of ready mixed concrete and assure you that improper testing by unqualified laboratories and personnel is a major problem.

We feel that the NAVLAP program is the best of any proposed accreditation programs available, and that it should not be discontinued. We believe that most, if not all of the costs of the program, can be supported by inspection fees.

This program uniquely offers the following features:

1. it currently is in place
2. as a government standard it can be widely recognized and accepted
3. it provides some measure of the competency of a laboratory
4. it can be self sustaining

We hope you may find these remarks useful.

Very truly yours,

Robert B. Nunley
Manager Materials Division

RBN/m

cc: NRMCA
Att: Dick Gaynor

Insta-Foam Products, Inc.
1500 Cedarwood Drive Joliet, Ill. 60435 · 815-741-6800 · Telex: 72-3415

February 9, 1982

Mr. John Locke
NVLAP Coordinator
National Bureau of Standards
Tech Building
Room B06
Washington, D.C. 20234

Dear Mr. Locke;

In response to the request of AALA and ACIL to take over the accreditation functions of NVLAP, I am personally not in favor of this. The NBS has a good reputation the world over, and I feel the program is going well under the present set-up. I feel there is good cooperation between NBS and the private sector.

If I can be of any service, please feel free to call on me.

Very truly yours,

R. L. Smith
Vice President-
Technical Director

RLS/jd

Appendix - 1

DESIGNING THE WORKSHOP

The American Council of Independent Laboratories (ACIL) and the American Association for Laboratory Accreditation (AALA) made certain suggestions to the Department of Commerce (DOC) about private sector participation in U.S. laboratory accreditation programs in general and in the Department's National Voluntary Laboratory Accreditation Program (NVLAP) specifically. ACIL suggested that DOC transfer the work of evaluating and accrediting laboratories from NVLAP to AALA. AALA in turn suggested that NVLAP be restructured to include provisions for the accreditation of accrediting organizations, such as AALA, which would in turn accredit laboratories.

The implications of the ACIL and AALA suggestions were far reaching both nationally and internationally, and it was concluded that a 2-day workshop should be held at which all interested parties would have an opportunity to express their opinions. The public announcement of the workshop along wiith the text of the ACIL and AALA letters were published in the Federal Register in August 12, 1981 (46 FR 40785 attached).

ACIL and AALA representatives and others from various sectors of interest in laboratory accreditation were invited to a workshop planning meeting at the Department of Commerce on July 7, 1981. Attending this meeting were:

Stanley Warshaw, Ph.D., NBS
Jack Williams, Ph.D., DOC
Gerald Berman, Ph.D., NBS
Mr. James Bryson, NBS
Mr. Armond Cardarelli, American Association of Motor Vehicle Administrators
Mr. John Locke, DOC
John Magnotti, Jr., Ph.D., AALA
Carl Morris, EPA
Mr. Louis Pritsker, Associated Laboratories, Inc.
Mr. Louis Rossi, AALA
Mr. Baron Whitaker, Underwriters Laboratories

The general scope and the specific subjects to covered at the workshop were discussed at this meeting. Five sessions were organized.

Session 1. Background of U.S. Laboratory Accreditation
Session 2. International Trade Implications of Laboratory Accreditation
Session 3. Need for Laboratory Accreditation
Session 4. Criteria for Recognizing Laboratory Accreditation Systems.
Session 5. A Mechanism to Accredit Organizations which Accredit Testing Laboratories.

Session 1 was to include definitions, highlighting the difference between laboratory accreditation and product certification, a description of the historical evolution of laboratory accreditation and DOC involvement, and a summary of current events in U.S. laboratory accreditation of particular relevance to the issues being considered. Session 2 was to include the implications of laboratory accreditation in foreign trade. Session 3 was to include a spectrum of observations from laboratories, manufacturers, an exporter, a regulator, and a consumer representative, addressed to the need for or the absence of a need for laboratory accreditation. Session 4 was to describe criteria and procedures which could provide a basis for recognizing laboratory accreditation systems. Session 5 was designed to permit AALA to explain in detail its proposal that NVLAP be converted to an accreditor of accreditation systems and to obtain discussion from workshop attendees.

The program, identifying speakers and brief abstracts of their talks, was published in the Federal Register on October 7, 1981 (48 FR 49630 attached). Appendix 2 presents brief biographical sketches of the speakers.

Federal Register
Vol. 46, No. 155
Wednesday, August 12, 1981

DEPARTMENT OF COMMERCE

Office of the Secretary

Public Workshop on Laboratory Accreditation; Future Directions in the United States

A two-day public workshop concerning present status and future direction of laboratory accreditation activities in the United States will be held on November 16–17, 1981, at the National Bureau of Standards in Gaithersburg, Maryland. The purpose of the workshop is to provide a public forum for the expression of views upon which recommendations could be developed to bring about a desirable and effective distribution of responsibilities between the government and private sectors in the area of laboratory accreditation.

The Department of Commerce (DoC) has operated the National Voluntary Laboratory Accreditation Program (NVLAP) since publication of the original NVLAP procedures on February 25, 1976. The stated goal of NVLAP is "to provide in cooperation with the private sector a national voluntary system to examine upon request the professional and technical competence of private and public testing laboratories that serve regulatory and nonregulatory * * * needs" (15 CFR Part 7a).

The original NVLAP procedures were amended so that other Federal agencies could fulfill their laboratory accreditation needs through NVLAP. Another amendment streamlined private sector use of NVLAP by encouraging private sector organizations, through due process procedures, to make a determination of need for a specific laboratory accreditation program (LAP) and to submit criteria for laboratory accreditation in that LAP.

The DoC has received two requests to amend further the NVLAP procedures. The first request (Appendix 1), from Roger J. Amorosi, President of the American Council of Independent Laboratories (ACIL), advocates the

testing, chemical testing, construction materials testing, electrical testing, thermal testing, mechanical testing, metrology, non-destructive testing, and optics and photometry. AALA currently has accreditied five laboratories and has a number of additional applications in process. Its financial structure is designed to be self-supporting.

A large number of laboratory accreditation programs are in operation both nationally

advocates transferring NVLAP's laboratory accreditation activities to the private sector and limiting the Federal Government's role to that of an accreditor of accreditation systems.

The workshop has been scheduled in response to these requests and in consideration of the growing importance of laboratory accreditation to international trade. The workshop program has been developed around the following key issues:

—Whether the DoC should cease its present role and substitute in its place a program to accredit organizations which, in turn, would accredit private sector testing laboratories.

—What, if any, additional measures should be taken to assure that an effective U.S. presence remains in international laboratory accreditation activities, including bilateral arrangements.

—What action, if any, can be taken by the private sector and/or the government to reduce the proliferation of inspections and paperwork arising from duplicative accreditation activities within the United States.

A second Federal Register notice is expected to be published in about two months and will contain a detailed agenda for the November meeting. Persons wishing to attend this workshop are invited to contact Mr. James O. Bryson, Chief, Office of Testing Laboratory Evaluation Technolgy, National Bureau of Standards, Washington, D.C. 20234 (301–921–2368).

Papers on the subject from interested parties will be considered for publication in the proceedings of the workshop. Such papers should be submitted by December 18, 1981. Authors are invited to provide notice, of their intention to submit a paper, to Dr. Jack Williams, Office of Product Standards Policy, Room 3876, Department of Commerce, Washington, D.C. (202–377–4148) indicating the title and general content of the material to be submitted, by September 1, 1981, if possible.

Dated: August 6, 1981.

Robert B. Ellert,

Acting Assistant Secretary for Productivity, Technology and Innovation.

Appendix 1

May 13, 1981.

Dr. Howard L Forman,
Deputy Assistant Secretary far Praduct Standard Palicy, U.S. Department af Commerce, Washington, D.C. 20230

Dear Howard: This letter is written on behalf of American Council of Independent Laboratories (ACIL) to respond to your letter dated March 6, 1981 commenting on the ACIL white paper entitled, "Independent Laboratories in 1981. Their Important Role, Their Critical Concerns." Your written comments were of great interest to ACIL and its members who share with you a common interest in an effective national program of laboratory accreditation. Because of the significant views expressed in your communication, the Executive Committee of ACIL has undertaken to review these points carefully in an effort to respond in a constructive manner. Inevitably, this process has delayed our response. In no way should this delay be interpreted as a lack of ACIL interest and concern about the problems which you have addressed.

There should be no misunderstanding about the respect which members of the independent laboratory community have for the efforts undertaken by the Department of Commerce to initiate a national voluntary laboratory accreditation program (NVLAP). While the program as initiated departed significantly from the original Department of Commerce plan, it nevertheless has made an effective contribution to a better understanding for the need for a *workable* national program. Additionally, it has served to resolve and address many of the technical aspects of how such a program must function to be credible. You will remember that the original plan envisioned by the Department of Commerce was to establish a quasi-public corporation which would administer a national program. A number of interested parties encouraged the Department to establish a program, whether quasi-public or wholly public, which was capable of recognizing in a coordinated procedural manner all aspects of a laboratory's capabilities. ACIL was disappointed when the Department failed to establish the NVLAP program on this basis. Nevertheless, ACIL has been consistently dedicated to trying to formulate a common approach which could meet the national and international needs for laboratory accreditation.

In 1977, Gene Rowland met with the Executive Committee of ACIL to confirm the specific procedure which the Department of Commerce intended to implement. As presented by Gene, this procedure required approximately 420 days to complete and covered only product categories. We expressed then and have expressed since our disagreement with a system which required so much time and placed such substantial burdens on the laboratory seeking accreditation. Almost five (5) years have passed and, as you report, only 5 programs have been initiated. To the best of our knowledge, only three have been implemented. We think that had the Department implemented its original plans more rapid progress would have been accomplished. It should be noted that very constructive measures have been taken by the Department to modify and improve the operation of the NVLAP program. Nevertheless, the Department has not, on its own initiative, determined that it is in a position to propose to recast substantially the NVLAP program to rely, to a maximum extent, on private sector organizations to administer such a program. We believe that the goal of NVLAP and private sector organizations interested in accreditation should be to transform NVLAP from an agency accrediting individual laboratories to an accreditor of private sector accrediting organizations. Strong precedents for this kind of Federal role exist in other fields such as education.

In this spirit, ACIL has been clear in expressing its view that NVLAP should be phased out as it now exists. The NVLAP staff can and should play an important role in participating in a transition to this new approach and ultimately serving as the accreditor of private accrediting organizations. In turn, the private sector should continue to work hard to assure that there are broad capabilities in the private sector to discharge the need to accredit laboratories of all kinds.

ACIL looks forward to further Department initiatives to establish proper Federal reliance on the private sector in meeting international and national needs for laboratory accreditation and pledges its continued cooperation with all interested parties to this end.

Sincerely yours,

Roger J. Amorosi,
President.

Appendix 2

July 6, 1981.

Dr. Stanley I. Warshaw,
Director, Office of Engineering Standards, Notional Bureou of Stondords, Department of Commerce, Woshington, D.C. 20234

Dear Dr. Warshaw: The American Association for Laboratory Accreditation (AALA) suggests that there is a need for the Department of Commerce, National Voluntary Laboratory Accreditation Program (NVLAP), to undertake to serve as the principal federal agency that would accredit private sector organizations as being competent to accredit testing laboratories and function as the U.S. government representative in the international laboratory accreditation community.

AALA is a non-profit organization formed in 1978 and chartered in the District of Columbia. Its purpose is to accredit the technical competence of laboratories performing testing service in various technical disciplines. It was patterned after the National Association of Testing Authorities—Australia (NATA) and was supported in its formation by contributions from diverse private sector sources. Its membership and participation is freely open to anyone. AALA is offering accreditation in the fields of acoustical and vibration measurement, biological (microbiological) testing, chemical testing, construction materials testing, electrical testing, thermal testing, mechanical testing, metrology, non-destructive testing, and optics and photometry. AALA currently has accreditied five laboratories and has a number of additional applications in process. Its financial structure is designed to be self-supporting.

A large number of laboratory accreditation programs are in operation both nationally and internationally. Information on these programs is contained in:

- *"Principal Aspects of U.S. Loboratory Accreditotion Program"* by C. W. Hyer, prepared under contract to DOC which indicates that some 70 laboratory accreditation systems are now operational within the United States.
- *"Internotionol Directory of Notionol Laboratory Accreditation Systems"* prepared by the International Laboratory Accreditation Conference (ILAC) which lists some 86 laboratory accreditation systems presently in operation throughout the world, and references nearly 20,000 laboratories having been accredited.

Because of the large number of laboratory accreditation programs, not all of the same competence and quality, and since many certification programs utilize laboratories to obtain test data as the basis for claims of conformity with standards, neither the manufacturer, consumer nor government have any basis to know if these laboratories are technically competent to provide the test data required to support these claims.

Industries and consumers require that laboratory results are reliable and are produced efficiently and with consistency. Accreditation of private accreditation systems will assure that a laboratory can perform competently and reliably to meet these needs.

International developments create a need for a unified public/private U.S. approach to the subject of laboratory accreditation. Under the General Agreement of Tariff and Trade (GATT), it is the obligation of the United States to "accept test results . . . issued by reliable bodies in the territories of other parts." This key position of GATT can be expected to have a significant impact on the United States. It is highly likely that the United States soon will be requested to accept test results produced by foreign laboratories.

To provide a uniform criteria for acceptance of the technical competence of laboratories, to facilitate the handling of these requests for approveal of the results of tests conducted by foreign laboratories and to provide a basis whereby all laboratories, domestic or foreign, may compete equally, we suggest that the most effective means to accomplish these goals is to transform the current National Voluntary Laboratory Accreditation Program (NVLAP) into a program to accredit accreditation systems in the private sector.

The precedence for the establishment of a program to accredit accreditation systems is supported by procedures already in operation in the United States' Department of Education for the accreditation of systems that accredit educational intitutions. This program has been operated successfully for a number of years and specifies criteria such as scope of operations; responsibility, to include clearly identified needs, responsiveness to the public interest, due process in accrediting procedures, and a willingness to foster ethical practices among the institutions and programs which it accredits; maintencance of program evaluation; reliability and autonomy.

The concept of accreditation by private sector organizations is consistent with the goals of the present administration to transfer certain federal programs to the private sector, It is apparent that laboratory accreditation programs can and should operate in the private sector since most private sector programs are designed to be financially self-sufficient. In so doing, this will tend to relieve the current burden on the federal budget. Transfer of the actual accreditation of laboratories to the private sector with the federal government performing in a different role as an accreditor of accreditation systems will act during a transition period to phase out existing NVLAP programs as private sector accreditation systems expand and refine their accreditation capabilities.

Once the concept of the government as an accreditor of accreditation systems is accepted, the criteria by which the government evaluates accreditation systems becomes of paramount importance. AALA has begun work to develop specific criteria that could be used in administering a government program to accredit private accrediting systems. It is our intent to make this criteria document available for comment by interested parties prior to the workshop which has been scheduled by the Department of Commerce on November 16–17, 1981.

Because to the general approach and organization of AALA, it is in a position to assume major responsibility for laboratory accreditation in the United States. It is understood, of course, that NVLAP in its function of accrediting accreditation systems will also be accrediting other systems whose purposes might be more highly directed to specific technical disciplines and products than is AALA's.

We look forward to the opportunity to work with the Department in developing this new approach further. Thank you for your consideration.

Sincerely,

Louis R. Rossi,
Chairmon.

[FR Doc. 81-23422 Filed 8-11-81; 8:45 am]

BILLING CODE 3510-13-M

DEPARTMENT OF COMMERCE

Office of the Secretary

Public Workshop on Laboratory Accreditation; Future Directions in the United States

In the Federal Register of August 12, 1981 (46 FR 40785–7), the Department of Commerce announced plans for a two-day public workshop concerning the present status and future direction of laboratory accreditation activities in the United States. That open workshop will take place on November 16–17, 1981 at the National Bureau of Standards in Gaithersburg, Maryland. Its purpose is to provide a public forum for the expression of views upon which recommendations could be developed to bring about a desirable and effective distribution of responsibilities between the government and private sectors in the area of laboratory accreditation. For further information, contact James Bryson at the Bureau's Office of Engineering Standards, telephone 301–921–2368.

This notice contains a detailed agenda (Appendix 1) for the November workshop. It also contains brief abstracts (Appendix 2) of the presentations to be made at the workshop. There will be opportunities for audience participation in the discussion periods following each session, except for session 2.

As stated in the notice of August 12, papers on any of the subjects of the workshop by interested parties will be considered for publication in the proceedings of the workshop. Such papers must relate to one or more of the issues to be discussed at the workshop. They should be submitted no later than December 18, 1981, to Dr. Jack Williams, Office of Product Standards Policy, Room 3876, Department of Commerce, Washington, D.C. (202–377–3221). In an effort to provide uniformity and facilitate reproduction, it will be helpful if the papers could be submitted in "camera-ready" format, and according to the following typing guidelines: Paper size 8½ x 11; margins; 1 inch all around; single space with elite type (12 characters per inch).

Issued: October 1, 1981.

Robert B. Ellert,

Acting Assistant Secretary for Productivity, Technology, and Innovation.

Appendix 1.—Agenda—Workshop on Laboratory Accreditation: Future Directions in the United States; November 16–17, 1981

November 16

9:00 A.M.—Introduction—*Stanley I. Warshaw,* Director, Office of Engineering Standards, NBS

9:10 A.M.—Welcome Address—*Ernest Ambler,* Director, National Bureau of Standards (NBS)

Session No. 1—Background of U.S. Laboratory Accreditation. *Stanley Warshaw,* Director OES/NBS, moderator. Panel (Questions after last speaker.)

9:30 A.M.—(a) Meaning of Accreditation and Certification—*Baron Whitaker,* Consultant to UL

9:45 A.M.—(b) History of Laboratory Accreditation in U.S.—*Theodore Young,* Consultant

10:05 A.M.—(c) Status of Laboratory Accreditation in U.S.—*Charles Hyer,* V.P. The Marley Organization

10:20 A.M.—Discussion

10:45 A.M.—Coffee break

Session No. 2:

11:15 A.M.-International Trade Implications of Laboratory Accreditation—*Douglas Newkirk,* Assistant U.S. Trade Representative for GATT Affairs

Session No. 3—Need for Laboratory Accreditation.

11:45 P.M.—Purposes of Accreditation—*John Locke,* Coordinator, National Voluntary Laboratory Accreditation Program (NVLAP) (Questions to follow).

1:00 P.M.—Lunch

2:00 P.M.—Panel on Advantages and Disadvantages of Laboratory Accreditation (Questions after last speaker). *John Locke,* moderator. Presentations from perspective of

(a1) Independent laboratory—Earl Hess, President Lancaster Laboratories

(a2) William Levelius, Vice President, Northern Region Pittsburgh Testing Laboratories

(b1) Manufacturers—(2) Richard Gaynor, Vice President for Engineering and Research, Ready Mixed Concrete

(b2) John Grant, Consultant to American Petroleum Institute

(c) Exporter—Frank Walters, Staff Engineer, Waterloo Project Engineering Center, John Deere

(d) State and local government—Donald Pinkerton, Executive Director, NCSBCS

(e) Federal regulator—Robert Alexander, Office of Standards Development, Nuclear Regulatory Commission

(f) Consumer Representative—David Swankin, Swankin & Turner

4:00 P.M.—Discussion

5:15 P.M.—End of 34rd Session

November 17

Session No. 4—Criteria for Recognizing Laboratory Accreditation Systems. *James Bryson,* Chief, Office of Testing Laboratory Evaluation Technology, NBS, moderator

9:00 A.M.—(a) On ASTM E-36 Work—*Gerald Berman,* Group Leader, Laboratory Performance Group, NBS

9:15 A.M.—(b) A certifier's view—*Theodore Pritsker,* President, Associated Laboratories

9:30 A.M.—(c) The AALA proposal—*Louis Rossi,* Chairman, of Board, American Association for Laboratory Accreditation (AALA)

9:45 A.M.—Discussion

10:15 A.M.—Coffee break

10:45 A.M.—(d) On IECQ—*Howard Kontje,* Chief Engineer, Underwriters Laboratories, Inc.

11:00 A.M.—(e) On ILAC—*Howard Forman,* Consultant

11:15 A.M.—(f) On OECD GLP—*Carl Morris,* Senior Scientist, Test Rules Development Branch, EPA

11:30 A.M—(g) On the State-of-the Art—*Theodore Young,* Consultant

12:00 P.M.—Discussion

1:00 P.M.—Lunch

Session No. 5—A Mechanism to Accredit Organizations Which Accredit Testing Laboratories. *Jack Williams,* Acting Director, Office of Product Standards Policy, Department of Commerce, Moderator

2:00 P.M.—AALA Proposal and Viewpoints—*Louis Rossi,* Chairman, AALA

3:00 P.M.—Discussion.

4:30 P.M.—Wrap-Up—*Stanley Warshaw*

5:15 P.M.—End of Workshop

Appendix 2.—Abstracts of Presentations

Presentation of *Baaron Whitaker, 9:30 a.m., Monday, November 16, 1981, 1a—15 minutes.*

Subject: *Meaning of Accreditation and Certification.*

This presentation clearly defines laboratory accreditation. Particular attention is given to the differences between laboratory accreditation and product certification. Related areas include:

- The meaning of accreditation to the laboratory user;
- The meaning of certification to the product user;
- The attributes which define a competent laboratory;
- Functions of a certifier over and above functions of a laboratory accreditor;
- Similarities in accreditors' and certifiers' assessment techniques.

Presentation of: *Theadare Yaung, 9:45 a.m., Monday, Navember 16, 1981, 1b—20 minutes.*

Subject: *History of laboratary Accreditatian in the United States.*

This presentation summarizes the evolution of accreditation in the United States starting with the earliest accreditation systems (DOA Federal Grain Inspection Service which was established in 1940) and identifies product areas for which accreditation programs were established roughly in chronological order. Special reference will be made to the Clinical laboratory Improvement Act (CLIA) system (the only system specifically identified in Federal Legislation) and the College of American pathologists system which is perhaps the largest non-governmental system in terms of number of accredited laboratories.

The presentation will conclude with a summary of events which led up to NVLAP.

Presentation of: *Charles Hyer,* 10:05 a.m., Monday, November 16, 1981, *1c—15 minutes.*

Subject: *Status af Laboratory Accreditation in the United States.*

This presentation provides the current and near future environment relative to laboratory accreditation, and describes how that environment seems to be affecting the operation of laboratory accreditation systems. Issues addressed will include the growth rate of laboratory accreditation systems, special product areas supporting growth in systems, any consolidation of systems, and percent of laboratories which have accreditation by more than one system. The relationship of public and private accreditation systems to businesses, trade associations, and professional associations will be summarized. A prognosis in what's ahead will conclude the presentation.

Presentation of: *Douglas Newkirk;* 11:15 a.m., Monday, November 16; *2—30 minutes.*

Subject: *Internatianal Trade Implications of Laboratary Accreditatian.*

This presentation will cover the significance of domestic and international laboratory accreditation activities for U.S. trade interests.

Presentation of: *John Locke,* 12:00 p.m., Monday, November 16, *3—30 minutes.*

Subject: *Purposes of Laboratory Accreditatian.*

Task Force C of the International Laboratory Accreditation Conference (ILAC) has prepared a report which describes some 10 or more reasons why laboratory accreditation is important. Detailed examples (foreign and domestic) illustrating each reason will be presented. Effects on all segments of the laboratory accreditation community will be summarized, as well as effects on international trade.

Panel Session on Advantages and Disadvantages of Laboratory Accreditation 2:00 p.m., Monday, November 16.

Presentation of: *Earl Hess, 3a1—10 minutes.*

Perspective: Independent Laboratory advocating accreditation of laboratories.

The nature of independent laboratory support of laboratory accreditation will be summarized. Advantages to the laboratory, to clients, and to the public will be described.

Presentation of: *William Levelius, 3a2—10 minutes.*

Perspective: Independent laboratory with many separate laboratory locations.

Concerns about accreditation of each independent site will be addressed in conjunction with how control of testing in separate locations is managed by the corporation. Similarities and differences between corporate control of the laboratories at separate locations and laboratory accreditation of those sites will be summarized. The advantages and disadvantages of each approach will be stated along with concerns about accreditation procedures themselves.

Presentation of: *Richard Gaynar, 3b1—10 minutes.*

Perspective: Manufacturer supportive of accreditation.

The effect of laboratory accreditation on the manufacturer will be described, along with advantages and disadvantages of using an outside accredited laboratory. Important qualities of an accreditor will be stated. An expression of general concerns with respect to laboratory accreditation will conclude the presentation.

Presentation of: *John Grant, 3b2—10 minutes.*

Perspective: Manufacturer with reservations about accreditation.

The effect of laboratory accreditation on manufacturers will be summarized, both for a manufacturer's laboratory and for an "outside" laboratory. Values used to judge competence of an outside laboratory will be described. Credentials which others seek when evaluating the work of a laboratory will be described. Concerns about and advantages of accreditation will conclude the presentation.

Presentation of: *Frank Walters, 3c—10 minutes.*

Perspective: Exporter.

The problems which a U.S. firm confronts when exporting a complex product will be summarized. Different perspectives from different countries in accepting test data will be noted. The implications of liability considerations in different countries and insurance considerations will be described. Desirable characteristics of a U.S. laboratory accreditation system important to the acceptance of test data internationally will conclude the presentation.

Presentation of: *Danald Pinkerton, 3d—10 minutes.*

Perspective: State and local governments.

State and local government code administrators have a special need for information about a product before they permit its use in their geographic area. Recognition of the competence of a testing laboratory is not sufficient for these purposes. The relationship between the needs of code administrators and laboratory accreditation will be described. Also the deficiencies of accreditation from the code administrator's standpoint and related concerns will be mentioned.

Presentation of: *Rabert Alexander, 3e—10 minutes.*

Perspective: Federal regulatory responsibilities.

Regulatory responsibilities which can be fulfilled by reliance on accredited laboratories will be described. The need for assuring the competence of testing laboratories will also be discribed. The advantages and possible disadvantages of accreditation to the government, to the regulated industry sector, and to the public will be summarized.

Presentation of: *David Swankin, 3f—10 minutes.*

Perspective: Consumers.

The importance of laboratory accreditation to consumer will be described. Other issues include: When is laboratory accreditation "good enough"? How can information about an accredited laboratory be used? What kind of information do consumers want about product tests? . . about accredited laboratories? The presentation will conclude by describing advantages of accreditation and consumer concerns.

Presentation of: *Gerald Berman, 9:00 a.m., Tuesday, November 17, 4a—15 minutes.*

Subject: *Generic Criteria for Laboratory Accreditation Being Developed by ASTM Committee E-36.*

This presentation describes the development of generic criteria of a laboratory accreditation system for the laboratory evaluation process and for assessment procedures. The discussion will focus on the necessary attributes of an accreditation system and will summarize the work of ASTM Committee E-36.

Presentation of: *Howard Forman,* 11:00 a.m., Tuesday, November 17, *4e—15 minutes.*

Subject: *Considerations in Recognizing Laboratory Accreditation Systems in Different Countries.*

This presentation covers the status of deliberations in the International Laboratory Accreditation Conferences (ILAC). The status of international agreements recognizing laboratory accreditation systems in two or more countries will be summarized. Efforts to develop international guidelines to judge laboratory accreditation systems will be summarized.

Presentation of: *Carl Morris,* 11:15 p.m., Tuesday, November 17, *4f—15 minutes.*

Subject: *OCED Agreement on Inspection Agencies in Member Countries.*

The OECD is proposing a complete system for the recognition and acceptance of animal test data among testing laboratories in different countries. This presentation will summarized the guidelines which the laboratory inspection agencies in each country should meet in order that data from testing laboratories in that country will be acceptable in other countries. Technical and administrative criteria will be described along with difficulties encountered in implementation of the scheme.

Presentation of: *Theodore Young,* 11:30 p.m., Tuesday, November 17, *4g—30 minutes.*

Subject: *Mechanisms for Acceptance of Accrediting Organization—the State-of-the-Art.*

This presentation summarizes the key factors used to accept or reject accrediting organizations in the U.S. Some of these examples come from fields other than laboratory evaluation, and the presentation will relate the relevant features of these programs to accreditation of laboratories. The administrative characteristics of accepting or denying accreditation will also be described.

Presentation of: *Louis Rossi,* 2:00 p.m., Tuesday, November 17, *5—One hour.*

Subject: *Transforming NVLAP Into a Program to Accredit Accreditation Systems.*

The American Association for Laboratory Accreditation (AALA) has proposed that NVLAP be converted from a laboratory accreditation system to an accreditor of such systems. In this presentating, AALA will describe just how it proposes that such a scheme would work. This discussion will include mechanisms' used by existing laboratory accreditation systems, such as those Federal and State governments.

Presentation of: *Theodore Pritsker,* 9:15 a.m., Tuesday, November 17, *4b—15 minutes.*

Subject: *Characteristics of Laboratory Accreditation Systems Which Certifiers Look For.*

This presentation identifies criteria which a product certification system manager would want in an organization which uses laboratories accredited by a laboratory accreditation system. Included are: (a) A certifier's concern for adequate testing; (b) relationships between a certifier and testing laboratories; (c) the question of product liability and (d) minimum requirements for an accrediation system.

Presentation of: *Louis Rossi,* 19:30 a.m., Tuesday, November 17, *4c—15 minutes.*

Subject: *An Accreditation System's View of What Makes a Good Laboratory Accreditation System.*

This presentation includes a detailed description of criteria recommended by AALA to be used by an organization (such as a Federal agency) which would recognize the competence of laboratory accreditation systems. Administrative procedures as well as technical characteristics will be covered.

Presentation of: *Howard Kontje,* 10:45 a.m., Tuesday, November 17, *4d—15 minutes.*

Subject: *The IEC's Way of Evaluating Certifiers in Participating Countries.*

This presentation describes the IEC's criteria for accepting member-country inspectorates. Although this is a certification scheme, the approved member-country inspectorate must accredit laboratories which test the products covered by the system. Also covered will be a description of the problems encountered in formulating the scheme and of potential future changes to the system.

[FR Doc. 81-29143 Filed 10-6-81; 8:45 am]

BILLING CODE 3510-BP-M

Appendix 2 - PROGRAM PARTICIPANTS

DONALD S. ABELSON

Director, Technical Trade Barriers, Office of the Special Trade Representative (STR). Responsible for coordination of the standards code activities. Chairman of the Subcommittee on Standards of the STR Trade Policy Committee. Member of the ANSI International Standards Council and the ASTM Committee on International Standardization. Formerly consultant to the Department of Commerce and the Federal Trade Commission on standards related issues.

ROBERT E. ALEXANDER

Chief, Occupational Radiation Protection Branch, Nuclear Regulatory Commission. Formerly Chief, Environmental Health Branch, NASA; head of health of physics, safety and hygiene programs at Atomics International, and reactor health physicist at Cenvair. Consultant to governments of Indonesia and Greece.

DR. ERNEST AMBLER

Director of the National Bureau of Standards

DR. GERALD A. BERMAN

Group leader in the Office of Testing Laboratory Evaluation Technology (OTLET) at the National Bureau of Standards (NBS) responsible for developing evaluation criteria, examination methods, and for assessing laboratories applying for accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP). He is the current chairman of ASTM Committee E-36 on Criteria for the Evaluation of Testing and Inspection Agencies. Formerly he taught at the University of Miami, Louisiana State University, and the University of Detroit where he served as chairman of the Electrical Engineering Department.

JAMES D. BRYSON

Chief, Office of Testing Laboratory Evaluation Technology, Office of Engineering Standards, National Bureau of Standards (NBS). A registered professional engineer, he has been engaged in a wide variety of investigations involving testing of structural materials and components. He managed the NBS Laboratory Evaluation and Accreditation Program (LEAP) and the Construction Safety Program before assuming his current responsibilities which includes managing the NBS technical support program for the National Voluntary Accreditation Program (NVLAP).

DR. HOWARD I. FORMAN, ESQ.

Consultant in areas associated with standards development, laboratory accreditation and patent law. Formerly Deputy Assistant Secretary of Commerce and Director of the Office of Product Standards Policy. He was a research chemist and attorney at the Frankford Arsenal before serving as patent and trademark counsel at Rohm & Haas Company. He is a U.S. Delegate to the International Laboratory Accreditation Conference (ILAC). Before his retirement he chaired the delegation at the four previous ILAC meetings.

RICHARD D. GAYNOR

Vice President of Engineering and Research, National Ready Mixed Concrete Association (NRMCA). He is chairman of ASTM Subcommittee C09.03.09 on Ready Mixed Concrete and ASTM Subcommittee C09.01.01 on the Cement and Concrete Reference Laboratory. Formerly engineer in charge of the NRMCA Joint Research Laboratory.

JOHN A. GRANT

Consultant representing the American Petroleum Institute, Division of Refines. He is Vice Chairman of ASTM Committee E-36 on Criteria for the Evaluation of Testing and Inspection Agencies. Formerly he was manager, Laboratory Services Division, AMOCO Oil Company and was responsible for quality control investigations and test method developments.

DR. EARL H. HESS

President, Lancaster Laboratories, Inc., Director of Government Relations, American Council of Independent Laboratories. Chairman, Small Business Division, Pennsylvania Chamber of Commerce; and a Member of the Board of Directors, Pennsylvania Technical Assistance Programs. Before establishing his laboratory in 1961, he was an industrial chemist, General Cigar Company, and a chemistry instructor at Franklin and Marshall College.

CHARLES W. HYER

Executive Vice President, The Marley Organization. Editor and Publisher of TMO Update. Formerly Assistant to the President, Electrical Testing Laboratories and Vice President and Director of Laboratories, York Research Corporation.

HOWARD C. KONTJE

Vice President, Follow-up Servies, Underwriters Laboratories, Inc. (UL). He represents UL on American National Standards Institute Committees and International Standards Organization Committees dealing with certification and quality control. He is chairman of the Finance Committee of the Electronics Components Certification Board, the U.S. National Authorized Institution for the International Electrotechnical Commission Quality Assessment Systems for Electronic Components (IECQ). Mr. Kontje was an engineer in the Electical Department of U.L. before joining the Follow-up Services Department in 1967.

WILLIAM H. LEVELIUS

Vice President, Northern Region, Pittsburgh Testing Laboratory (PTL). He is a Member of the Board of PTL and is responsible for corporate-wide quality assurance among over 50 PTL laboratories across the country. Mr. Levelius is a Registered Professional Engineer in eleven states. He managed PTL's Milwaukee and Chicago laboratories before moving to Pittsburgh.

JOHN W. LOCKE

Coordinator, National Voluntary Laboratory Accreditation Program (NVLAP), U.S. Department of Commerce. Formerly a trade association executive; president of his own consulting company; executive director of the Consumer Product Safety Commission; consultant in systems analysis with Booz, Allen and Hamilton NUS Corporation; and an operations researcher and advanced design engineer in the aerospace industry.

DR. JOHN F. MAGNOTTI JR.

President, MACO Associates Ltd., an association multiple management firm. Executive Director, American Association for Laboratory Accreditation; Executive Vice President, National Association of Small Government Contractors; Executive Vice President, The American Speciality Surety Council. Formerly, Vice President, Corporate Affairs Administration, The BDM Corporation; Executive Vice President, National Council of Professional Services Firms; Assistant Vice President, Planning Research Corporation.

DR. CARL R. MORRIS

Senior Scientist, Test Rules Development Branch, U.S. Environmental Protection Agency. Chairman, OECD Expert Group on Good Laboratory Practices. He is on the editorial board of the International Journal of Regulatory Toxicology and Pharmacology. In the past, was assistant director of a regional cancer center; assistant professor of urology, oncology and pharmacy, University of Tennessee. Other research and teaching assignments were at: Medical University of South Carolina; University of North Carolina; University of Texas; and University of Wisconsin.

DONALD S. PINKERTON

Executive Director, National Conference of States on Building Codes and Standards, Inc. (NCSBCS). He represents NCSBCS at various standards organizations ANSI, ASTM, NFPA, and UL) at the local code organizations (BOCA, ICBO, SBCCI) and at the National Governors Association. He was formerly Director, Department of Housing and Community Development, State of California, and Mayor, City of Fairfield, California.

DR. THEODORE P. PRITSKER

President, Associated Laboratories, Inc., Chairman of ASTM Committee E-6 on Building Construction and member of ASTM Committees E-36 on Laboratory Accreditation and F-40 on Product Liability. He serves as chairman of the ISO Technical Advisory Groups, 160 on glass and 162 on windows and doors. He is a registered professional engineer. Formerly he was a project engineer at Allied Chemical.

LOUIS R. ROSSI

Manager, Administration Division, Research and Testing Laboratory, PSE & G Research Corporation. He is Chairman of the Board, American Association for Laboratory Accreditation; Chairman of a new subcommittee on discipline standards guidelines of ASTM Committee E-36; and was a member of the U.S. Delegation to the International Laboratory Accreditation Conference (ILAC).

DAVID SWANKIN, ESQ.

Partner, law firm of Swankin and Turner. Represents a number of consumer groups and professional associations. Formerly Executive Director, White House Office of Consumer Affairs; Deputy Assistant Secretary of Labor for Labor Standards.

FRANK WALTERS

Staff Engineer responsible for homologation - (the worldwide compliance of tractors to international standards and regulations) at the - John Deere Waterloo Product Engineering Center. Chairman of the U.S. Delegation to ISO TA 23 for Agricultural Equipment; Chairman of ISO TC 23.2 on Common Tests; Advisor to the U.S. OECD delegate on agricultural equipment; Vice Chairman, SAE Construction and Agricultural Machinery Council. Mr. Walters has been involved in the design development and testing activities of John Deere for over 36 years, the past twenty-one years focused on worldwide technical issues.

DR. STANLEY I. WARSHAW

Currently Director, Office of Engineering Standards at the National Bureau of Standards (NBS). Formerly Director, Center for Consumer Product Technology at NBS. Previously at American Standard, Inc. he served as: general manager, development and engineering; manager, materials and chemistry; manager, ceramic technology; and research supervisor.

BARON WHITAKER

Consultant to the President, Underwriters Laboratories, Inc. (UL). He is on the Executive Standards Council of the American National Standards Institute (ANSI); on the certification committee (CERTICO) of the International Standards Organization; is an alternate on the U.S. National Committee of the International Electrotechnical Commission (IEC). He was President of UL from 1964 to 1978; and has been a member of the U.S. Delegation at all International Laboratory Accreditation Conferences. He is recipient of the Howard Coonley Medal for leadership in the advancement of the national economy through voluntary standards.

THEODORE R. YOUNG

Consultant in laboratory accreditation issues. Formerly at the National Bureau of Standards responsible for laboratory accreditation issues and Coordinator, National Voluntary Laboratory Accreditation Program. Previous to that he was Chief of the Metrology Division at NBS.

NBS-114A (REV. 2-80)

U.S. DEPT. OF COMM. **BIBLIOGRAPHIC DATA SHEET** *(See instructions)*	1. PUBLICATION OR REPORT NO. NBS SP 632	2. Performing Organ. Report No.	3. Publication Date March 1982

4. TITLE AND SUBTITLE

Laboratory Accreditation: Future Directions in the United States
Proceedings of a Workshop held at the National Bureau of Standards,
Gaithersburg, MD, on November 16-17, 1981

5. AUTHOR(S)

John W. Locke, Editor

6. PERFORMING ORGANIZATION *(If joint or other than NBS, see instructions)*

NATIONAL BUREAU OF STANDARDS
DEPARTMENT OF COMMERCE
WASHINGTON, D.C. 20234

7. Contract/Grant No.

8. Type of Report & Period Covered

Final

9. SPONSORING ORGANIZATION NAME AND COMPLETE ADDRESS *(Street, City, State, ZIP)*

Same as No. 6

10. SUPPLEMENTARY NOTES

Library of Congress Catalog Card Number: 82-600525

☐ Document describes a computer program; SF-185, FIPS Software Summary, is attached.

11. ABSTRACT *(A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here)*

The purpose of the Workshop sponsored by the National Bureau of Standards was to provide a public forum for the expression of views upon which recommendations could be developed to bring about a desirable and effective distribution of responsibilities between government and private sectors in the area of laboratory accreditation. The Workshop was initiated in response to two related requests to change the Department of Commerce's (DoC) National Voluntary Laboratory Accreditation Program (NVLAP) in order that NVLAP's laboratory accreditation activities would be transferred to the private sector and DoC's role would be limited to that of an accreditor of accreditation systems.

As a basis for initiating public comment, 20 invited participants presented papers in five sessions: 1) background of U.S. laboratory accreditation; 2) international trade implications of laboratory accreditation; 3) need for laboratory accreditation; 4) criteria for recognizing laboratory accreditation systems; and, 5) a mechanism to accredit organizations which accredit testing laboratories. Approximately 200 people attended the Workshop and the written and oral reviews of all who participated are summarized in these Proceedings. Also included are written comments (letters) which were sent in by participants and other interested persons after the Workshop was concluded.

12. KEY WORDS *(Six to twelve entries; alphabetical order; capitalize only proper names; and separate key words by semicolons)*

Criteria; definitions; history; international trade; laboratory accreditation; need.

13. AVAILABILITY

☒ Unlimited
☐ For Official Distribution. Do Not Release to NTIS
☒ Order From Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.
☐ Order From National Technical Information Service (NTIS), Springfield, VA. 22161

14. NO. OF PRINTED PAGES

172

15. Price

$6.50

☆U.S. GOVERNMENT PRINTING OFFICE: 1982-360-997/2054

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